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EUROPEAN AGRICULTURE OF THE FUTURE

THE ROLE OF PLANT PROTECTION PRODUCTS

ECONOMIC IMPACTS

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Founded in 1981 and located in Bologna, Nomisma is an economic research institute with more than 80 shareholders, including industrial groups, insurance companies, and Italian and foreign banks. "Nomisma" is an ancient Greek word that signifies "the real value of things": it is in this spirit that Nomisma operates as an observatory on the main trends in the real economy and contemporary society. Nomisma engages in research at international, national and local levels focused on production factors, on the economics of sectors and businesses, on development problems and – in general – on the trends that affect the structure, the behaviour and outcomes of contemporary economics.

The study was undertaken following requests from various companies and organisations operating in the agri-food sector to provide a scientific evaluation of the potential impact on European agriculture resulting from the proposed new regulations on market access and use of crop protection products. The study benefited from various contributions and sponsorship from BayerCropScience and Syngenta.

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INTRODUCTION

European agriculture is currently undergoing a period of profound change, due to various factors. This study has focused on the role of Plant Protection Products (PPPs), used in agriculture to manage pests, diseases and weeds and representing a critically important technological tool in ensuring the productivity and quality of agricultural output. The use of these products in the European Union today occurs within the framework of specific norms that regulate their access to the market and define maximum residue levels (MRLs) allowed in food. The main regulatory instrument concerning PPPs is Directive 91/414/EEC, which during the next few months will undergo a process of revision regarding the PPPs admitted to the EU market. This process has contributed to a progressive reduction of the availability of PPPs for EU farmers. In addition, a new regulation, which will replace the current directive and comprises some innovative elements (for example, cut-off criteria and comparative assessment), is presently under discussion. This proposed regulation could further limit the availability of PPPs.

The analysis developed in this second part of the study is focused on the quantitative definition of the potential impacts linked to the application of the current and future legislation. The main part of the analysis concentrates on three case studies (wheat, potatoes and wine grapes). This approach was necessary because the various agricultural crops are characterized by profound differences in terms of their responses to phytosanitary treatments. On the basis of these results, it was also possible to define the impact for cereals, which remain the most widely diffused crops in Europe. The results show that the role of PPPs in the productivity of plants is decisive. In a 2020 scenario, EU production of wheat, potatoes and wine grapes could be effected by declines in yield of 29%, 33% and 10%, respectively, assuming that access to PPPs is reduced as expected under the new regulation that will replace Dir. 91/414/EEC.

These results allow confirmation of the indications that emerged from the first part of the study that was published in September 2007. A general drop in EU agricultural productivity will lead to a decline in the EU's raw material self-sufficiency, thus to an increased vulnerability to world market price fluctuations and growing dependence on extra-EU imports with ensuing reduced guarantees for food safety and quality of European food products. Negative economic impacts on employment and value creation in the Agri-food sector and its numerous associated economic activities (wholesale and retail trade, services to companies, financial activities and transport, etc) would be generated. Additionally, further restrictions on PPP market access can also have a negative impact on the ability of R&D-based companies to develop new and innovative products that are less hazardous for humans and the environment, safer to use, and more effective against evolving pest threats, due to less than satisfactory rates of return on investment. Thus the impacts will not only be confined to the agrochemical sector, but will affect the entire European economic system.

With this research Nomisma seeks to make its own contribution to knowledge, hopefully providing a useful tool for decision makers who are asked to express their opinion on the new proposal for regulating access to the market for PPPs. The original approach employed allows evaluating several aspects that were not taken into consideration in previous impact evaluations of the new regulation.

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1 THE LEGISLATION ON PLACING PLANT PROTECTION PRODUCTS (PPPS) ON THE MARKET

THE REGULATION ON PPPS

Over the last two decades most developed countries have been dedicating significant resources to their R&D and administrative sectors in order to improve the safety of PPP use. These efforts were aimed at developing more selective products to better ensure protection of the environment and safeguarding of human health, fostering Integrated Crop Management (ICM), and improving local assistance in PPP management, while responding to the challenge of growing interest in organic farming.

In the EU-27, such environmental and safety guarantees are even more comprehensive than in other developed countries due to the effect of strict regulations covering the placement of PPPs on the market and maximum residue levels (MRLs) allowed in food.

PPPs used to protect plants or plant products are mainly regulated by Directive 91/414/EEC "on the placing of plant protection products on the market". The Directive states that Active Substances (ASs) cannot be used in plant protection products unless they are included in an EU positive list. An EU programme of evaluation to revise this list is currently under way. Chemical substances or micro-organisms (including viruses) in PPPs are only approved for use if they have undergone a scientific risk assessment, and safe use has been demonstrated through a peer-reviewed safety assessment. Once a substance is included in the positive list, applicants can ask Member States to authorise marketing and use of PPPs containing it.

The risk assessment mentioned above refers to the estimation and the evaluation of all potential acute and long-term effects of storage, handling and application of PPPs on humans and non-target organisms in general as well as on the environment. Under EU law, safety of humans and animals and protection of the environment are considered to be more important than protection of crop production. Consistency between good agricultural practices in the use of PPPs and defined safety thresholds (i.e. maximum residue levels in food) must be demonstrated before market access is granted to PPPs.

Currently, there are no specific regulations to monitor the correct use of these products by farmers. Following clear label instructions and best agricultural practices, farmers are supposed to make every effort to avoid unacceptable risk of damage to the environment and to human health. Sustainable Use legislation was recently proposed in order to incorporate rules on PPP use into the existing legislative framework. The purpose of the proposed Directive on Sustainable Use of PPPs is to create a legislative framework establishing a set of guidelines that must be observed to allow profitable integrated farming following the best agriculture practices over a long-term perspective. The following package of measures outlined in box 1 comprises the main elements of the European Commission's strategy for PPPs.

In the next sections attention is focused on the EU legislation that regulates the market access and the use of PPPs-legislation which is in now undergoing a process of review.

BOX 1 | **EUROPEAN COMMISSION'S STRATEGY FOR PPPS**

	OBJECTIVE	REGULATION CURRENTLY IN PLACE	OBJECTIVE
PPP Industry	Access to the market through in-depth and extensive scientific assessments (human health, environment, etc.)	Dir. 91/414/EEC Reg. (EC) No 1490/2002 Reg. (EC) No 2229/2004 Reg. (EC) No 1095/2007	Proposal for regulation to replace Dir. 91/414/EEC
Farmers	Provide farmers with proper label instructions; Train farmers and monitor correct use of PPPs	Dir. 91/414/EEC	Proposal for regulation to replace Dir. 91/414/EEC Proposal for Directive on Sustainable Use of PPPs
Consumers	Set, monitor and control PPP residues (MRLs) in products of plant and animal origin	Dir. 76/895/EEC Dir. 86/362/EEC Dir. 86/363/EEC Dir. 90/642/EEC Reg. (EC) No 396/2005	No new proposals as focus is on implementation of most recently introduced MRL legislation

Source: Nomisma elaborations on European Commission information.

DIRECTIVE 91/414/EEC

OBJECTIVES OF THE REGULATION

The European Union has been regulating the market access and the use of Plant Protection Products (PPPs) with specific legislation since 1991, when Directive 91/414/EEC – The Council Directive of 15 July 1991 concerning the placing of plant protection products on the market – was issued.

The Directive, which went into force a few years later, after the legislation was adopted by all Member States, was aimed at achieving many objectives, in particular, the following:

1. harmonizing the rules applied by each Member State in governing the authorization of PPP use; these rules, which vary substantially between Member States, presented a barrier to both trade in PPPs and, even more important within the overall EU economy, plant products;
2. providing a high standard of protection, preventing access to the market and use of products with unacceptable risks to human health, groundwater and the environment, the protection of which is of higher priority than improvement of crop yield.

The driving element in the evaluation of ASs within PPPs, as proposed by the Directive, is the assessment of the risk related to their application and use, with risk being defined as the effects of the potential hazards multiplied by the levels of exposure of humans and the environment to the AS:

RISK = HAZARD x EXPOSURE

- Risk: the real possibility of damage or suffering from potential harm or danger;
- Hazard: a potential source of danger or harm;
- Exposure: the voluntary/non-voluntary act of being subject to an action or an influence.

In other words, the driving principle of the Directive states that the evaluation of an AS or a PPP is not related to its intrinsic toxicological (hazards), but to the relationship between these and the controlled or incidental exposure of humans, wildlife and the environment.

It must be emphasised that, in any case, the submission of an AS or a PPP to evaluation under Dir. 91/414/EEC was required to take into account Council Directive 79/117/EEC, which prohibits the placing on the market and the use of plant protection products containing certain active substances: this Directive called for a pre-selection of ASs based on the evaluation of their risks.

The legislative scheme defines a process for evaluating new active substances (ASs) that seek market access and a process for reviewing existing ASs that are already marketed as PPPs under the new harmonized rules.

With regard to existing ASs, a detailed plan of review grouped ASs into 3 priority lists, with a precise schedule, interim milestones and a deadline for completion of the whole process. The planned period for completion of the review was originally set at 10 years. This period was defined for the review of all the existing ASs, therefore all the priority lists. The deadline was then subject to subsequent postponements and the overall review is still not fully completed today. Finally, the Directive stated that substances within PPPs included in the positive list for market access should be reviewed periodically in order to take into account developments in science and technology and the wider scale impact of the actual use of these products for plant protection.

EFFECTS OF DIR 91/414/EEC APPLICATION

It has been 16 years since the issuing of the Directive, with most of the ASs having already undergone review; however, work towards completion of the review is still ongoing and hopefully will be completed within the next 12 months. We summarize the strengths and weaknesses of Dir. 91/414/EEC in the following section (box 2).

Directive 91/414/EEC certainly demonstrated some strengths and has shown that it was an appropriate legislative tool to reach some of the proposed objectives.

BOX 2 | **DIRECTIVE 91/414/EEC: SWOT ANALYSIS**

STRENGTHS	**WEAKNESSES**
– Progressive but effective harmonization of rules across EU achieved – Clear criteria to assess risk, demonstrate safe use, propose appropriate risk management, submit evaluation dossier identified	– Time schedules not met, with continuous postponement of deadlines, especially regarding the review of existing ASs – ncomplete legislation required subsequent upgrades (i.e. harmonisation of MRLs), elimination of "real" trade barriers slower than planned – Investments needed for the review detracted resources from research on new safer PPPs – "safe use" is not (and is not) perceived by EU Consumers
OPPORTUNITIES	**THREATS**
– Ensure harmonization of all legislation referring to PPPs; ensure that market players can refer to clear rules, steps and deadlines – Stimulate research technology improvements through fast-track access to market for low-risk products – Align legislation and authorization paths for all PPPs including semiochemicals, growth regulators, preservers, etc. – Provide adequate availability of appropriate tools for plant protection of minor crops	– Major reduction of PPPs available for EU farmers – Obsolescence of the remaining PPPs, due to low rate of new introductions, PPP R&D no longer as productive as in 1978–1993

Source: Nomisma elaborations.

It must be acknowledged that, in a highly complex and varied environment with diverse levels of focus, commitment and resources, the process of legislative harmonization was actually quite successful (for example, the Authorities responsible for PPP evaluation were and still are very different in various countries: in the UK it is the PSD, a specialized and dedicated Agency; in France, the Ministry of Agriculture and Fisheries; in Italy, the Ministry of Health). All EU countries have been improving their ability to apply the harmonized rules, therefore progressively meeting the key objectives of the Directive 91/414/EEC.

Efficient exchange of information and cross-country cooperation obviously require some time to achieve, but the level of cooperation has progressively improved.

Another element of strength was identified as the definition of clear criteria for producing a dossier and demonstrating acceptable or unacceptable risk of each AS, as well as proposing safe use and risk management tools. Despite the fact that some key elements that had to be taken into consideration were missing or "under way" and then re-addressed or fine-tuned during the implementation phase, the criteria for evaluation are well defined.

In addition to the above-mentioned strengths, some key weaknesses of the Directive and its implementation and impact on the PPP market can be highlighted.

The major weakness appears to be an inaccurate estimation of time schedules and financial consideration. The Directive set very high standards and established ambitious deadlines for the review of known ASs, but these standards and deadlines were never reached and they are far from being achieved now, with deadlines still being continuously postponed. The timing of implementing the Directive has been unpredictable since the very beginning, and as a consequence the economics of the crop protection business have been affected by a high level of uncertainty.

Unpredictability was also increased by subsequent upgrading and fine-tuning of legislation and processes that were necessary to address all requirements related to the objectives of the Directive (i.e. MRL harmonization across EU Member States has not yet been achieved and was addressed in 2005 with Regulation EEC No 396/2005, while new guidelines for implementation of Dir. 91/414/EEC are constantly being introduced without a clear process).

A further weakness is the detraction of resources from research aimed at developing new PPP compounds and technologies in order to fund the review process of known ASs: the PPP industry had to sustain large investments to maintain market access of already known ASs and products by demonstrating their safe use within the Directive guidelines. These resources were thus no longer available for research and technology upgrading and led to lower rates of introduction of new ASs (as shown below).

The last, but not least, weakness is that "safe use" was not (and is not) perceived by EU Consumers, whose perceptions of the hazards and risks of PPPs and their residues in food appear to be quite high in a recent survey. A Eurobarometer survey in 2005 clearly identified pesticides residue as being included in the list of external factors that are "at the top end of the worry scale on which consumers express concern...", with the majority of EU citizens (71%) claiming to be worried about pesticides residues in food, vegetables and cereals.

Considering that the legislation is aimed at "safe use" and protection of human health, that investments in evaluating safety and appropriately managing risk are huge, that data from monitoring have never raised any major concerns, the lack of reciprocal recognition of these extensive efforts by EU citizens must be considered a major weakness of the current system.

The above-mentioned strengths and weaknesses were identified by the main stakeholders that are affected by legislation and implementation of regulations regarding PPPs. Extrapolating from these strengths and weaknesses, it was possible to identify opportunities for improvement of legislation and processes, as well as the threats that might arise for EU consumers, environment, agriculture and the PPP Industry from the weaknesses in the Directive and its implementation.

All relevant (specific and non-specific) legislation needs to be harmonized and simplified, providing market players with clear guidelines and reference procedures. Market players should also be able to follow clear steps and strict deadlines, which are needed for an appropriate evaluation of economics, business plans, budget allocations, and overall feasibility of investments.

A fast-track procedure could be defined and implemented for ASs and PPPs that clearly demonstrate low hazards and health and environmental risks in their manipulation and use, thus stimulating research in this direction. This already occurs, and very effectively, in other countries: the Environmental Protection Agency (EPA), the U.S. Federal Agency that supervises the introduction and use of PPPs in all of the United States, except California, has implemented a specific and efficient procedure for preliminary assessment of new PPPs to hasten entry to market for those that are identified as posing low risk.

Evaluation rules and criteria should be harmonized for all PPPs and those products, other than nutrients, that influence life processes in plants, therefore including pheromones, growth regulators, preservers, etc.

Finally, there is a need for appropriate legislative tools and appropriate procedures that will allow market availability of PPPs, not only for those crops that are considered economically interesting by the Industry investing in them, but for all the crops that make up the EU's varied agriculture, landscape and environment, its wide variety of food products and the related "gastronomic" culture of its territories.

At the same time, the progressive reduction of the number of ASs and PPPs authorized in the Member States of the EU should be avoided (table 1). Over the last several years, as required by Directive 91/414/EEC, the market availability of various ASs has been progressively subject to revision. Since 1993, the effect of the Directive has been that 57.2% of the ASs covered by the legislation can no longer be authorised for use in the EU.

TABLE 1 I **STATUS OF ASs UNDER EU REVIEW (DOC. 3010)**

STATUS	NUMBER	SHARE
Included in annex I*	167*	15.2%
Not included in annex I**	629	57.2%
Pending or notified***	304	27.6%
TOTAL ASs	**1,101**	**100.0%**

*Substances included in Annex I to Directive 91/414/EEC, and that therefore can be authorised in the EU (of which 74 "new" after 1993).
**Substances not included in Annex I to Directive 91/414/EEC, and that therefore cannot be authorised in the EU.
***Substances for which the evaluation is still ongoing. Pending any decision, they can be authorised in the EU (of which 55 new ASs).

Source: Nomisma elaboration on data from EU-DG Health and consumer protection (Update 13/12/2007).

The loss of ASs available for EU farming, due to non-inclusion in Annex I, is not by any means compensated for by the entry of new actives released by research activities: 629 ASs were not included, while only 74 have been included as new ASs and entered the market and 55 are currently listed as pending (thus under evaluation) as new ASs.

The reduction of ASs available on the market thus might also occur as a result of the reduced capacity to identify new breakthrough PPP technologies and the lower rate of deliveries from research in this segment, mainly due to the activities and investments of the agrochemical industry.

This lower rate of discovery, which is also reducing the rate of new market entries, coupled with constantly smaller numbers of known substances that survive the review process, poses a threat to the freedom of choice of EU farmers in selecting appropriate tools for management of pests and the resistance risk. Furthermore, there is the risk of obsolescence of a whole range of PPPs on the market, which will not be replaced by new, environmentally and user friendlier solutions for crop protection.

The above-mentioned concerns need to be considered in the new legislation and procedures, taking into account the main threats as mentioned above. These challenges can be addressed by adopting legislative tools that, while respecting the principles of Directive 19/414/EEC and the objective of increased protection of human health and the environment, also will allow stimulating and supporting research on crop protection.

TOWARDS THE NEW LEGISLATION

Discussion on the areas in which Dir. 91/414/EEC can be improved has been very active since the beginning of the implementation process. This debate was made public in 2001, when, at the end of July, the Commission submitted a progress report to the Council and the Parliament on the functioning of Dir. 91/414/EEC.

The conclusion of the report was that a reform of legislation was needed and the Commission, Council and Parliament identified, among others, the following objectives that are reiterated below:

- the reinforcement of the high level of protection of human health and the environment;
- the improvement of the functioning of the internal market, increased transparency and the harmonization of availability of PPPs for farmers from different countries of the EU;
- the ethical need to avoid repetition of animal testing (on vertebrates);
- the exclusion of substances with very hazardous profiles though precise selection criteria;
- the introduction of a simplified procedure for low-risk substances and products;
- the strengthening of the competitiveness of EU research capacities and the EU chemical industry;

from a procedural standpoint, one of the specific objectives;

- the definition of the role of the European Food Safety Authority (EFSA).

From the discussion and analyses that followed, a new proposal for Regulation (Proposal for a Regulation of the European Parliament and of the Council concerning the placing of Plant Protection Products on the market) was presented by the Commission in July 2006. The proposal for upgrading of the PPP market access legislation was based on considerations suggested by the Commission itself, with the EU Council and Parliament and stakeholders from agriculture, the PPP Industry and the public participating in the discussion.

In summary, the proposed change in legislation, which will assume the status of a Regulation in order to ensure consistent and simultaneous implementation in all 27 Member States, with reduced administrative burdens and improved clarity for economic actors, consists of the following key elements:

A) The EU will continue to maintain a single positive list of active substances for use in PPPs, with appropriately established criteria for approval;

B) The EU will have a positive list for safeners and synergists and a negative list for coformulants, with appropriately established criteria for approval/rejection;

C) Member States will continue to authorize use of PPPs;

D) data protection and data sharing criteria will grant 10 years of protection to studies that are considered as necessary for an authorization (or modification of it), but will not be granted for the revision of renewal of the Authorization. Furthermore, data sharing of vertebrate studies will be achieved either through voluntary (agreement among parties) or compulsory (imposed by MS) decisions;

E) The EU will be split into 3 authorization zones (North, Central, South) and mutual recognition of PPPs will be granted to notifiers in MS belonging to same zone (and regardless of zone for applications in greenhouses and post-harvest). National Provisional Authorizations (NPAs) currently issued by Rapporteur Member States for faster access of PPPs to market will be abolished;

F) Hazard-based criteria (cut-off criteria) will be introduced to exclude ASs from positive lists before and regardless of any risk assessment; the criteria address hazards to both human health and the environment;

G) a fast-track procedure will be adopted to speed up access to the market for PPPs that contain low-risk substances, synergists and safeners;

H) comparative assessments of substances will be made and updated, with consequent identification of those that are candidates for substitution. A list of products containing substances identified as candidates for substitution will be prepared.

Finally, the proposal seeks to accelerate the approval of active substances, and even more important than speeding up the process, it establishes precise deadlines for each procedural step, which can be used as a reference by the industry in planning investments on the basis of future returns: steps and timing issues have been summarized in Figures 1 and 2.

THE NEW ELEMENTS PROPOSED IN THE REGULATION

Having identified the strengths and weaknesses of the current legislation (Dir. 91/414/EEC), along with their associated opportunities and threats, we seek to analyze whether and how the proposed Regulation improves the overall legislative framework relevant to PPPs and addresses the proposed objectives.

The analysis is performed by focusing on the key elements of change as summarized above.

First of all, the choice of upgrading the legislation by means of a Regulation should certainly lead to higher level of harmonization across the EU and among all the MS, with changes being made throughout EU territory and within all Member States simultaneously and in a consistent manner.

It is in the interest of all economic stakeholders to be able to refer to a single procedure for management of all the active substances, to have equal access to all PPPs available in the EU and to operate in a competitive environment with the same, fair and clear rules adopted by all countries. Yet differences between national conditions will still exist: these are "protected" under a process of authorization that, while giving MS access to substances approved at the EU level, leaves it up to each MS to issue the approval of PPPs that can be used in national territory.

The effective implementation of the Regulation should be facilitated by the progress made in recent years by Authorities of each MS in cooperating with partners, in sharing information and methodologies, and eventually, in undertaking the slow but effective application of Dir. 91/414/EEC.

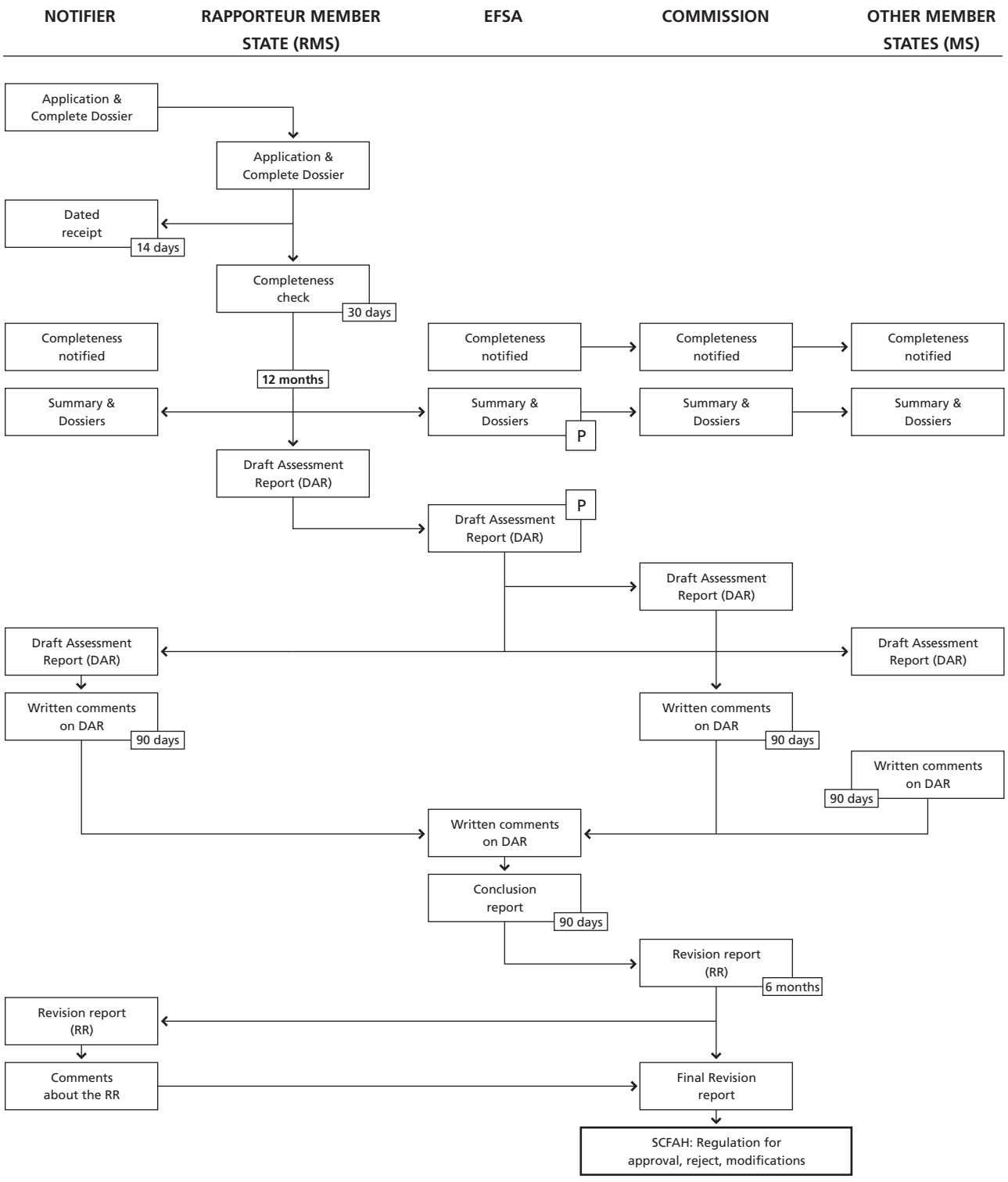
POSITIVE LISTS EXTENDED TO SAFENERS AND SYNERGISTS, NEGATIVE LISTS FOR CO-FORMULANTS;

As important components of PPPs, with specific effects on the biology of plants and non-target organisms, safeners and synergists appear to require specific evaluation (risk assessment) under the same criteria adopted for active substances.

Since each component (substance, synergist, safener) must be independently submitted to evaluation/review and given that all the components are simultaneously present in a particular PPP, problems might arise for Industry and farmers in identifying which stage of the lifecycle of PPPs might be affected by expiration/non-renewal of authorization of specific components.

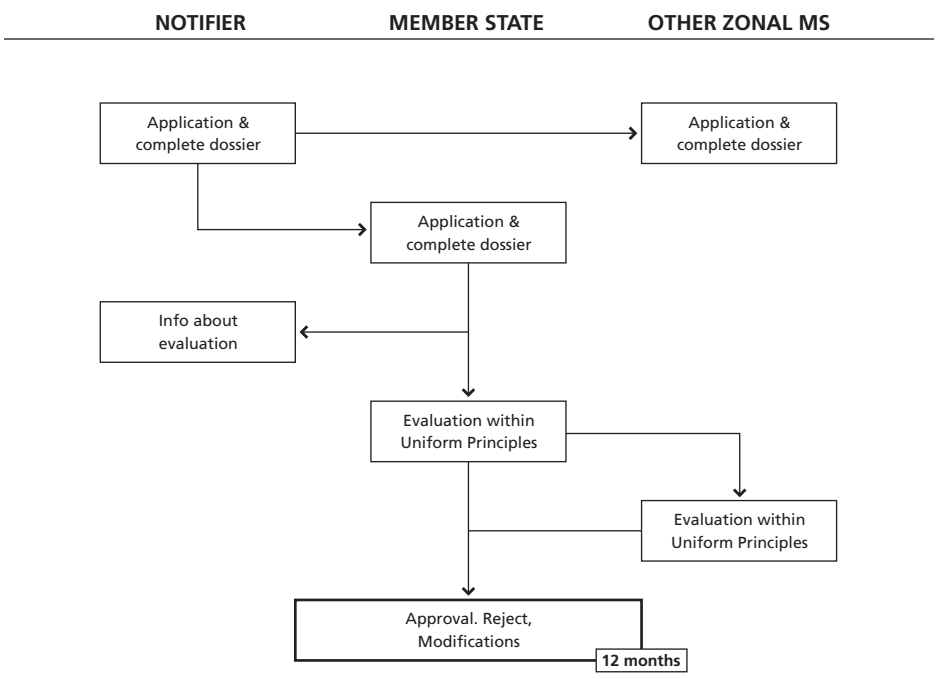
Major efforts in planning and an effective system of alignment of milestones are needed in order to ensure that a fair and competitive environment and a wide choice of products for farmers are maintained.

FIGURE 1 | **PROCEDURE FOR THE APPROVAL OF AN ACTIVE SUBSTANCE FOR PPPs**



Source: translated from Desideri et al., 2007.

FIGURE 2 I **PROCEDURE FOR THE APPROVAL OF A PPP AT MS LEVEL**



Source: translated from Desideri et al., 2007.

DATA PROTECTION AND DATA SHARING RULES

The proposed Regulation ensures that the company applying for authorization (Notifier) will enjoy data protection for its original, relevant and compliant studies and tests for a period of 10 years.

An exception on ethical grounds is being proposed for those studies involving vertebrate animals. Such studies should not be repeated in order to avoid inflicting additional suffering on animals, provided that there is appropriate and transparent cost-sharing among interested parties with regard to the original study.

It is also proposed that data protection should not be applicable to studies submitted for the renewal of registration.

The debate on data protection is intense, since the timing of data protection and the types of studies that are protected can have a significant impact on the economics of both the research-based and the generic industry. Certainly, an equilibrium between the need to protect intellectual property and the need to maintain the competitiveness of the industry and offer a wide choice of options for farmers must be reached. It is important to emphasise that a higher level of protection of human health and the environment can only be achieved through continuous research and development, and that the slower rate of introduction of new substances indicates that the discovery of new plant protection solutions is becoming more and more difficult and requires increasing investments.

Regulations that provide an incentive to those who invest in research, by making research more attractive from a business perspective, are better suited to address the objectives of the proposed Directive.

Within this context, it is necessary to adopt a data protection period that adequately takes into account the requirements of research-based companies for a satisfactory return on investment: the increasing risks and capital-intensity of research that are borne by such companies need to be recognised through appropriate protection of intellectual property.

The data protection period defined in the new regulation should help ensure that research on new crop protection solutions is not just exclusively focused on major crops/pests – which may provide quick returns on investments due to the large market size and potentially substantial revenues. There must also be attention dedicated to solutions for medium/minor crops in order to continue to make available a large variety of crop protection tools that will permit the survival of the wide range of crops grown by EU farmers.

MUTUAL RECOGNITION AND DELETION OF NATIONAL PROVISIONAL AUTHORIZATION

Three zones in Europe were identified as having similar climatic, environmental and agriculture conditions (the debate about the possible division of the EU into 4 zones is still ongoing), in which the holder of an authorization may apply for registration under same conditions (same label) in a different MS under the mutual recognition procedure. According to EU legislation, each MS will retain the freedom to impose stricter rules related to the protection of operators and bystanders from exposure to ASs and PPPs.

Mutual recognition will certainly allow a reduction of duplicated efforts and costs sustained by evaluating Authorities and by companies applying for authorization. Furthermore, it will hasten access to the market, at least in countries within the same zone, thus granting equal access to production inputs for farmers operating in similar agriculture environments. Voluntary mutual recognition across zones, while still under discussion, would further extend the possibility for equal access to production-enhancing inputs when relevant. Specific procedures for mutual recognition are already successfully in place in some Member States (i.e. Germany), and the concept of the zone, with its associated risks, uncertainties and opportunities, is being evaluated in all three zones.

The National Provisional Authorizations (NPAs), which are currently issued by Rapporteur Member States (RMS) to allow accelerated access of PPPs that are included in Annex I to local markets, will be abolished.

It is important to emphasise here that the NPAs issued by the RMS currently require an average of 2–4 years for Authorization in other MS and do not address the need for harmonized availability of PPPs in the different MS.

It must also be mentioned that the NPA was a tool used by the PPP Industry to speed up access to a market of interest by making a targeted choice of the RMS, thus starting as early as possible to gain returns from the large investments made in developing the PPP (the PPP industry has one of the highest ratios of "research investments vs. returns").

Under the proposed new Regulation, quick access to the market will be ensured only if the strict milestones for evaluation and authorization of both ASs and PPPs are reached. If such requirements are not met, even the use of a tool such as the NPA would not compensate for the longer time to market access, and the interest in making further investments in research will be reduced.

THE INTRODUCTION OF CUT-OFF CRITERIA

The introduction of cut-off criteria apparently signals a significant change in approach from the one that inspired Directive 91/414/EEC, which, as previously reported, was purely based on risk assessment.

We say "apparently" because in recent years some EU countries have already adopted cut-off criteria, though these were independent and non-coordinated moves at the national level. For example, there was the ban applied by the Italian Authorities on all products classified as CMR 1 and 2 (substances that are classified in categories 1 & 2 for carcinogenicity, mutagenicity or toxicity to reproduction). Moves such as this unilateral decision have generated clear dissimilarities in evaluation criteria and created unequal accessibility conditions for products across the EU.

The proposed hazard-based cut-off criteria focus on safety for humans, with the exclusion of CMR 1 and 2 and endocrine disruptors (which alter the normal activity of endocrine systems with impact on growth, embryonic development, reproduction and behaviour of organisms). They also focus on protection of the environment, with the exclusion of substances that are persistent, bioaccumulating and toxic (PBTs).

The adoption of clearly defined cut-off criteria for a pre-selection of substances that might become (or remain) usable in PPPs could also become a way to improve harmonization of the

positions of different MS and could contribute to stimulating research towards development of safer and more effective PPPs. Furthermore, the choice of criteria that can be easily understood by the average citizen will help EU consumers form an improved opinion of PPPs.

Still, the cut-off criteria should be scientifically sound, based on the "inspiring principles" of the legislation and should provide industry and research with clear reference elements that will be useful in defining research strategies and investments.

A FAST-TRACK PROCEDURE FOR AUTHORIZING MARKET ACCESS OF LOW-RISK PPPS

A specific procedure to ensure the fastest possible access to market for PPPs that contain low-risk active substances, safeners and synergists, together with an extended period of approval of 15 years for the substance, will certainly stimulate research in this direction, by granting Notifiers quicker and longer returns on their investments.

This procedure will have a direct impact on one of the key objectives of the proposed Regulation which is "the reinforcement of a high level of protection of human health and the environment".

THE INTRODUCTION OF COMPARATIVE ASSESSMENT

The proposed Regulation introduces the practice of comparative assessment, with specific criteria that are to be used to evaluate substances. Additionally, the Regulation states that a list of candidates for substitution will be established at the EU level.

The criteria adopted are hazard-based and, as mentioned above, refer to the comparison among the approved substances with regard to the potential hazards to the following:

A) Human health: substances with an Acceptable Daily Intake (ADI), and/ or Acute Reference Dose (ARfD) and/or Acceptable Operator's Exposure Level (AOEL) which are significantly lower than the average of the substances approved for PPPs will be included in the list of candidates for substitution.

B) Environment: substances that meet 2 of the criteria to be considered PBTs (see cut-off criteria) will be approved as candidates for substitution.

The Member States will then decide on the denial of access or withdrawal of authorization for a PPP on the basis of a comparative risk assessment.

The comparative assessment approach reintroduces hazard-based evaluation elements, despite the fact that the substances have already passed the following: a) selection due to application of the cut-off criteria; b) successful completion of the risk assessment, with risk management and risk mitigation measures in place.

The cut-off criteria appear to be a legislative guideline that might be considered controversial, but at the same time concretely define conditions for access to the EU market, thus providing clear indications for research and investments. On the other hand, the comparative assessment approach appears to be much vaguer, therefore reducing market certainties that would justify development efforts and investments in research. Additionally, the latter approach will subject evaluators, especially at the MS level, and industry to the huge administrative burden of an endless evaluation. Last but not least, a continuous, and not always scientifically sound debate might arise in order stimulate/inhibit decisions of refusal/withdrawal of authorizations.

CONSIDERATIONS ON CRITICAL ELEMENTS

The regulation proposed by the European Parliament and the Council concerning the placing of PPPs on the market has some key elements which are likely to be critical for the future of a wide range of products that are needed for effective pest control. These critical elements will also have

an impact on the future of EU agriculture and its capacity to ensure quality farm products at affordable prices.

Among these critical elements there are some that can certainly have a very positive impact, and should be fine-tuned to ensure fair competition within industry and stimulate research on safer PPPs.

Others appear to contradict the objectives of the proposed Regulation and will subject industry, evaluators and administration to excessive and not necessarily justified administrative burdens.

- A faster, more reliable procedure for the approval of ASs and PPPs, supported by a procedure for mutual recognition, is needed and would be welcomed. There needs to be some assurance that the proposed strict deadlines for the completion of evaluation and authorization procedures will be met by the relevant authorities, also to compensate for the abolishment of NPA, which played a key role in speeding up returns on investment in research.
- Data protection should be defined in a manner that stimulates investments in research aimed at developing safer PPPs and technologies through ensuring adequate returns that justify such investments for a wide range of crops/pests and not only for those that, thanks to their critical mass, ensure fast returns.
- Cut-off criteria, the main criteria of the proposed legislation, can be accepted as a preliminary access filter (despite the fact that being hazard-based somewhat contradicts the "risk assessment" approach), provided that they are scientifically sound, correctly address research concerns and do not limit the opportunities for availability of a wide range of ASs and PPPs. It must be emphasised that it is important to avoid a further major reduction of ASs and PPPs available on the market due to the ban on a large number of existing ASs, as the market gaps created by the absence of such products will not necessarily be adequately filled by new "less hazardous" plant protection solutions.
- Comparative assessment appears to be an unpredictable limiting factor that, following application of cut-off criteria plus risk assessment, generates useless administrative burdens and provides the system with an unpredictability that makes investments in research very unattractive.
- The fast-track procedure for low risk PPPs, on the other hand, should help stimulate research towards PPPs that are safer to humans and the environment and should be strongly supported.

A final, very important consideration refers to the precise timing and strict deadlines which the proposed Regulation imposes for each step of the evaluation: as reported in Figures 1 and 2, a timeframe of 2.5 years is planned for completion of all the steps required to evaluate a substance, while 1 year is planned for the evaluation of a PPP.

These clearly defined time parameters will certainly be of major help to the industry, thus allowing it to properly plan business development and evaluate potential returns on investment based on reliable timeframes. The commitment to respecting deadlines will therefore enhance certainty, making investment in research for new PPPs more attractive. With the availability of clear information on the authorisation process regarding PPPs, also farmers will have the possibility to plan and possibly accelerate changes and improvements in the agricultural technologies and processes they adopt.

In order to ensure a positive future for EU agriculture, it is crucial that this commitment is met, and that all the players involved in the evaluation of ASs and PPPs, EFSA, EU and MS offices prepare themselves to respect the proposed deadlines.

An efficient system that attracts investments will improve its overall profile, making PPPs safer and ensuring environmental protection, satisfying investment returns, increasing efficiency and

reducing the costs of administration, which is paid for by EU citizens, while improving the competitiveness of the industry. Having evaluated all the key driving elements of the proposed new regulation on placing PPPs in the market, an additional analysis based on their impact on PPPs currently available is also required.

The starting point of this analysis is the rapid decline in the number of ASs available on the EU market since 1993, as mentioned above. The new proposal was therefore analysed in order to understand the likely number of active substances that would be affected by non-approval ("cut-off") criteria and criteria to identify "candidates for substitution". The respective conclusions of the European Commission and the European Crop Protection Association (ECPA) differ substantially, as shown in table 2 below.

TABLE 2 I **PREDICTED IMPACT OF CRITERIA IN THE NEW PROPOSAL: SHARE OF PPPS AFFECTED**

	COMMISSION EVALUATION	ECPA EVALUATION
Trigger non-approval criteria	5%	30%
Candidates for substitution	15%	Up to 50%
TOTAL AFFECTED	**20%**	**60%**

Source: Nomisma elaboration of European Commission and ECPA data.

The Commission considers that some substances, for which the Dir. 91/414/EEC review has yet to be completed, would not be withdrawn from the market for reasons other than the exclusion criteria. ECPA, however, believes that a more holistic approach must be taken, as the impact on the market appears to be high and many substances are at risk of being classified in the future, with the adoption of the criteria that have been identified in the proposal.

However, the present draft directive on sustainable use also contains a set of short-term measures aimed at reducing the use of PPPs with clear restrictions under certain specific conditions.

In any case, it appears clear that despite the differences existing between the relevant evaluations of the Commission and the ECPA, a further reduction of 20% in the number of ASs available will present major challenges to farmers in terms of freedom of choice in their economic activities. In the worst case, a reduction of 60% would be dramatic for a system of agriculture that is highly variegated in terms of crops, pests, soil, climate and growing patterns, and, despite addressing the "prioritaire" safety of humans and environment, such a development would also be contradictory to the EU policy that aims to protect all the positive features of EU agriculture and the beneficial effects on the EU environment, landscape, culture and lifestyle, as well as the much-needed competitiveness of its economy.

A possible solution could be offered by the further expansion of R&D activities to develop innovative products that are more effective with lower impacts on health and the environment, even though the current proposal does not offer sufficient elements to stimulate further research, especially in terms of the uncertainties in the time to market required and the return on significant investment.

An overview of the scientific publications produced by research-based companies in recent years has revealed that the R&D pipelines bringing new products to market have been getting drier and drier, and that many of the "ASs of the future" would fail to satisfy the new "cut-off" criteria. These developments have raised the strategic issue as to whether it is realistic to expect research and discovery processes to introduce a large number of less hazardous, safer and more effective plant protection solutions to the market in the years to come.

2 ROLE OF R&D AND INNOVATION IN THE PLANT PROTECTION INDUSTRY IN EUROPE

INTRODUCTION

Companies producing plant protection products (PPPs) experienced a period of significant growth during the 1970s and 1980s. Yet by the 1990s, the world PPP market faced serious challenges: crops that were more resistant to disease and pests and changing regulatory requirements. The latter were motivated by increasing social and government concerns about health and environmental effects of PPPs. These developments were accompanied by changes in cultivation practices and support measures due to CAP reforms as well as fluctuations in world commodity markets. Thus, companies that produced PPPs had to make significant investments in research and development in order to address the changes in market conditions, both in adapting products to modified plant characteristics and developing products that will continue to be approved by relevant registration bodies. The agrochemicals industry has also undergone a series of mergers and acquisitions, leading the 7 largest companies to account for 85% of world sales.

R&D: EUROPE AND USA

The most recent European Commission report (Key Figures 2007 on Science, Technology and Innovation, 2007) shows that EU-27 R&D intensity in general has stagnated since the mid-nineties. In 2005, only 1.84% of GDP was spent on R&D in the EU-27 – down slightly from the 1.9% reported in Key Figures 2005, reflecting data up to 2003. Overall EU R&D intensity remains lower than in the US or Japan, with rates of 2.67% and 3.17%, respectively. If current trends continue, China will catch up with the EU in terms of R&D intensity by 2009. This trend suggests a diminishing weight of Europe in the increasingly globalised sphere of science and technology: the EU-27 share of global R&D investment is now around 25%, compared with 29% a decade ago (table 3). Yet a significant part of this gap is due to Enlargement – the New Member States all registered below EU-average R&D intensities, though several countries did show better results than the southern European old Member States. Consequently, due to various structural difficulties in reaching the 3% target, the Lisbon Strategy was revised in 2005 with each individual Member State now setting its own target for R&D intensity.

In 2005 total world R&D spending (GERD) reached nearly US$ 908.4 billion (€ 729,7 billion at average annual 2005 exchange rates), with the EU-27 accounting for 25%, compared to 34.4% for the US (table 3). While US R&D spending was significantly higher than EU R&D spending (nearly US$ 85 billion more), both areas have lost shares of the R&D total mainly to Asia, and particularly to China, which increased its share of world R&D expenditure from 3.6% in 1995 to 12.7% in 2005. USA remains the largest single investor in R&D, followed by Japan and Germany.

The overall gap in R&D intensity between Europe and USA continues to persist. However, it needs to be pointed out that in the area of chemicals and chemical products (including PPPs) the differences in R&D intensity between the EU and US are not significant, and the European chemicals industry is actually somewhat larger, with a higher R&D intensity (DG Research, 2007). In 2003, the share of business enterprise R&D (BERD) of the chemicals and chemical products industry as a share of GDP in the EU-27 was 0.25% compared to 0.21% in the US, whereas its value added as a share of GDP was 1.76% in the EU-27 and 1.73% in the US. In the same year, BERD as a share of value added of the chemicals and chemical products industry was 14% in the EU and 12.1% in the US. In the agrochemical industry (a branch of specialised chemicals), major R&D efforts in Europe tend to be concentrated in only a few EU countries – Germany, the UK and France – where the largest R&D-based agrochemical companies and some non-EU companies have research facilities – as well as Switzerland. At the global level, the total investment in R&D spent

by the major agrochemicals companies in 2005 was US$ 2.28 billion (valued at around € 1.83 billion at average 2005 exchange rates), which represented 0.25% of total public and private R&D.

TABLE 3 | **TOTAL R&D EXPENDITURE (GERD) FOR THE MAJOR WORLD REGIONS, 1995 AND 2005**

	PURCHASING POWER PARITY $ 1995		PURCHASING POWER PARITY $ 2005	
	Mil. $ (current)	%	Mil. $ (current)	%
Europe	**147,588**	**30.8**	**242,102**	**26.7**
EU-27°	139,438	29.1	227,543	25.0
North America	**195,390**	**40.8**	**334,309**	**36.8**
USA	184,077	38.4	312,535	34.4
Asia	**114,025**	**23.8**	**282,522**	**31.1**
Japan	76,182	15.9	118,026	13.0
China	17,399	3.6	115,197	12.7
Oceania	**6,248**	**1.3**	**12,678**	**1.4**
TOTAL	**479,002**	**100**	**908,394**	**100**

* Purchasing Power Parity: Financial aggregates are sometimes expressed in terms of PPP, rather than in ecu/euro based on exchange rates. PPP are based on comparisons of the prices of representative and comparable goods or services in different countries in different currencies on a specific date. The calculations on R&D investments in real terms are based on constant 2000 PPP. Actual exchange rates vary from the PPP levels for various reasons, such as the demand for imports or investments between countries.
* EU-27 does not include Bulgaria.

Source: DG Research, 2007; Data: OECD. Key Figures 2007.

R&D IN THE CHEMICALS SECTOR: THE ROLE OF PPP INDUSTRY

Chemicals represent a key sector in the global economy and an important driver of global R&D investment. At the global level, the chemicals sector (including activities related to plant protection products) was ranked 6th in terms of R&D investment, totaling € 17.186 billion or 4.7% of overall corporate R&D investment by the world's top 1400 companies. The chemicals sector registered a nearly 10% increase in R&D investment in 2006, whereas in 2005 R&D levels had experienced negative growth.

As a specialised branch of the overall chemicals sector, the world crop protection market in 2006 recorded sales of over US$ 30.4 billion (around € 24.2 billion), with Europe accounting for 30.3% of this market (in terms of sales destination). The 2006 level represented a drop of –2.5% in dollar terms from the peak of nearly US$ 31.2 billion (around € 25.08 billion) registered in 2005.

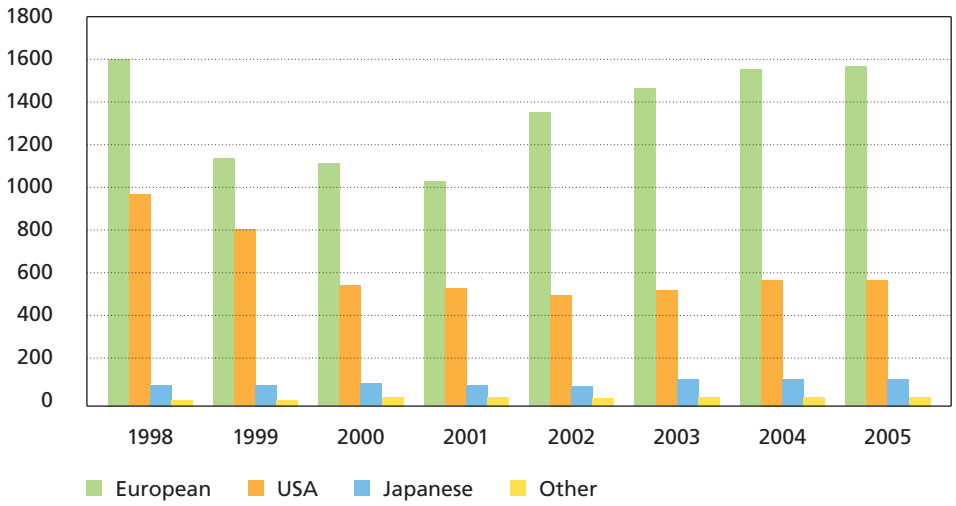
Figure 3 shows the trends in R&D spending related to PPPs. There was a sharp decline (more than US$ 700 million) in overall R&D spending in 1998–2002. After 2002, spending on R&D rose again; however, the 2005 level was still substantially lower than that recorded for 1998 (US$ 390 million less).

A series of mergers and acquisitions during the 1990s through 2001 led to a consolidation of the R&D capacities of companies that produce PPPs. The number of multinational and large companies performing R&D in the crop protection field has decreased from 15 to 10. Many of the companies active in the industry in the 1970s and 1980s have either sold their agrochemical activities or been merged or acquired by the current large players. For example, Bayer Crop Science incorporates the former Bayer Crop Protection, Aventis CropScience, AgrEvo (Hoechst + Schering), Roussel Uclaf, FBC (Fisons + Boots + Hercules), Rhone-Poulenc, May & Baker, Union Carbide, Mobil and Achem. Syngenta has absorbed the former activities of Novartis, Ciba Geigy (Ciba + Geigy),

Sandoz, and Zeneca (ICI + Stauffer) (Pallett, 2005). Now there are only three major R&D-based players in the PPP industry based in Europe and three in the USA – these top six companies now account for more than three-quarters of the world market.

The changes in the market (fewer players, stricter regulations in Europe, more costly processes for new molecule discovery, such as combinatorial chemistry and genomics, and biological and biochemical screening, reduced PPP demand in some major markets such as the US, etc.) have led to a situation in which only the larger consolidated companies are able to sustain the high cost of research aimed at discovery of new active substances. There has been considerable rationalisation of R&D facilities in the industry, ranging from the phasing out of certain capabilities and activities to site closures. More than a dozen R&D sites have closed in Europe alone since the 1990s (CPM, July 2006).

FIGURE 3 | **REGIONAL TRENDS IN R&D SPENDING BY MAJOR AGROCHEMICAL COMPANIES* 1998–2005 (US$ MILLION)**



*Bayer, Syngenta, BASF, Monsanto, Dow Agrosciences, DuPont, MAI, Sumitomo Chemical, Nufarm, FMC.

Source: Nomisma elaboration of data from Phillips McDougall, 2007.

Table 4 below shows the most recent available data on sales and R&D investment by 10 leading companies involved in production and sales of agrochemicals. Overall investment in R&D by the three major PPP-producing companies based in Europe in 2006 amounted to US$ 1,579 million – a total that remained unchanged from 2005 in dollar terms – with R&D intensities varying from 7.7% to nearly 11%. Industry sources estimate that around US$ 1 billion of research is conducted in Europe by European and non-European companies.

The research intensities for the major R&D based agrochemical companies in 2005 and 2006 are much higher than in the overall chemical industry (which covers a wide range of chemical products and processes and had an R&D intensity of 3.1% in 2005). Furthermore, the R&D intensity of the European-based companies for 2006 is 9.3%, far higher than the average rate for the competing firms, though FMC, Dupont and Sumitomo have R&D intensities that are at the levels of the major R&D based European firms.

In comparison to the large R&D-based companies, spending on R&D by companies that mainly produce generic or off-patent products is only about 1–2% of sales (Brookes 2006) – as seen for the companies MAI and Nufarm in the table above. The generic companies have benefited from the availability of many molecules moving to post-patent status and have seen their sales increase, while several of the R&D based firms have experienced recent sales declines due to a more competitive market.

TABLE 4 | **MAJOR AGROCHEMICAL COMPANIES' SALES AND RESEARCH INTENSITIES 2005–2006 (US$ MILLION)**

	SALES			R&D SPENDING			R&D INTENSITY
	2005	2006	2006/2005	2005	2006	2006/2005	2006
Bayer	6,917	6,723	–2.8%	694	670	–3.5%	10.0%
Syngenta	6,330	6,378	0.8%	509	490	–3.7%	7.7%
BASF	4,097	3,863	–5.7%	376	419	11.4%	10.8%
Monsanto	2,910	3,136	7.8%	35	40	14.3%	1.3%
Dow	3,094	3,105	0.4%	235	235	0.0%	7.6%
Dupont	2,250	2,210	–1.8%	215	200	–7.0%	9.0%
MAI	1,543	1,581	2.5%	21	19	–9.5%	1.2%
Sumitomo Chemical	1,290	1,281	–0.7%	110	110	0.0%	8.6%
Nufarm	1,189	1,245	4.7%	15	16	6.7%	1.3%
FMC	725	767	5.8%	72	74	2.8%	9.6%
TOTAL MAJOR COMPANIES	**30,345**	**30,289**	**–0.2%**	**2,282**	**2,273**	**–0.4%**	**7.5%**
European	17,344	16,964	–2.2%	1,579	1,579	0.0%	9.3%

Source: Nomisma elaborations on data from Phillips McDougall, 2007.

RATE OF DISCOVERY AND REGISTRATION

Despite access to increasingly sophisticated and costly technologies, the rate of discovery of new molecules in the PPP industry has declined. Estimates on how many molecules need to be screened in order to come up with an active substance that can be effectively and safely placed on the market have varied over the years: decreasing from around 1 in 11,000 molecules screened in the mid-1960s (Berg et al, 1999, cited in Pallett, 2005) to around 1 in 50,000 by the mid-2000s (Evans, 2006). Bijman (2001) states that only one out of 200,000 compounds eventually becomes a new plant protection compound. Most of the easily discovered compounds have already been found over the past few decades, leaving those that are more complex and less obvious – thus more costly to discover and formulate.

At the same time, increasing restrictions in the EU market will allow fewer molecules on the market, thus making the ability of companies to develop formulations that are acceptable under the new regulations coupled with the safest and most effective application modes even more important.

An ideal active ingredient must satisfy several essential characteristics while also addressing increasingly rigid regulatory criteria. A product needs to be effective and sustainable from an economic perspective, while at the same time easy to use without risks to human health and the environment.

Developing new active substances generally takes 8–10 years (ECPA, 2006). Thus, not only must cost be considered in investment decisions, but also the time to market – a critical factor in maintaining competitiveness. During 1995–2000, the average lead time between the first synthesis and first sale of a PPP increased from 8.3 to 9.1 years (Phillips McDougall, 2003). Lengthier and more rigid registration requirements increased the cost of development and testing. While in the 1980s and 1990s, more than 12 new active ingredients per year were introduced on average, in the most recent period (2000–2006) this rate has declined to only 10 per year, reflecting lengthier and more costly R&D and registration phases (table 5). A consequence of higher R&D costs is that very little investment is going into products for minor crops such as vegetables. New compounds are generally only being developed for major crops such as maize, wheat, soybeans, and cotton (Bijman and Joly, 2001).

An earlier Phillips McDougall study showed that the costs of bringing new PPPs to market have increased steadily over the years: in 1975–1980 these averaged US$ 23.1 million and rose to US$ 152 million in 1995 and US$ 184 million in 2000 (in terms of comparable annual ecu/euro exchange rates posted by the US Federal Reserve Bank, these figures for 1995 and 2000 were € 117.5 million and € 199.3 million, respectively). During 1995–2000, total research costs increased 30.6%, while total product development costs of the 10 largest agrochemical companies increased by 17.9% (at nominal value), driven mainly by rising costs in field trials (38.9%) and environmental chemistry (23.1%) (Phillips McDougall, 2003). Euros Jones of ECPA indicated that it now costs on average € 3.6 million to update an EU dossier (CPM, June 2006).

Once an active substance is registered, it can also be extended to a new crop category (for example, minor crops such as vegetables) or to additional countries. If a company determines that there is sufficient marginal expected profitability, then an extension of use must be requested, requiring the generation of additional data on efficacy, safety and residue levels. The costs of extension of use requirements can be as high as an additional € 1.2 million (Brookes, 2006).

As seen in Table 6 below, out of the US$ 2.250 billion (€ 1.809 billion) spent on R&D in 2004, the Discovery phase of R&D activity is the most cost-intensive in the process of bringing new products to market. In 2004 the major R&D based companies spent over US$ 705 million (around € 567 million) on this phase. Companies also spend about a quarter of their R&D budget on the costs of managing and improving existing product lines.

In terms of scientific discipline and activity, the breakdown of R&D expenditure in 2004 is presented in Figure 4 below. Chemistry and Biology account for the largest shares of this expenditure, accounting for 30.4% and 31.5%, respectively, of R&D spending. Registration activities and fees accounted for 12.4% of the amount spent on R&D.

In addition to adhering to increasingly stricter EU registration requirements for PPPs, products must also be submitted to national registration systems – National Provisional Authorisations (NPA), which are to be abolished under the new proposed PPP regulation. It has generally been quicker to receive registration at the national level (23 months following submission of required EU dossier, compared to 68 months for EU authorisation (Brookes, 2006)) to allow introduction at the Member

TABLE 5 | **PRODUCT INTRODUCTIONS AND R&D BY CROP (1980–2006)**

NUMBER OF NEW ACTIVE INGREDIENTS		**TIME PERIOD**			
PRODUCTS	**CROPS**	**1980–1989**	**1990–1999**	**2000–2006**	**IN R&D**
Herbicides	Cereals	15	12	10	4
	Soybean	11	10	1	0
	Maize	2	10	6	4
	Rice	11	19	6	6
	Fruit & Veg	2	1	0	0
	Other	10	5	2	1
	TOTAL	**51**	**57**	**25**	**15**
Insecticide	Fruit & Veg	11	16	7	8
	Rice	5	2	3	0
	Cotton	9	12	1	2
	Others	4	7	5	6
	TOTAL	**29**	**37**	**16**	**15**
Fungicides	Fruit & Veg	13	8	12	7
	Cereals	14	16	8	5
	Rice	9	5	5	3
	Others	0	0	0	4
	TOTAL	**36**	**29**	**24**	**19**
Others		7	3	4	0
TOTAL		**123**	**126**	**70**	**50**
AVE. ANNUAL RATE OF INTRODUCTION		**12.3**	**12.6**	**10.0**	**10.0**

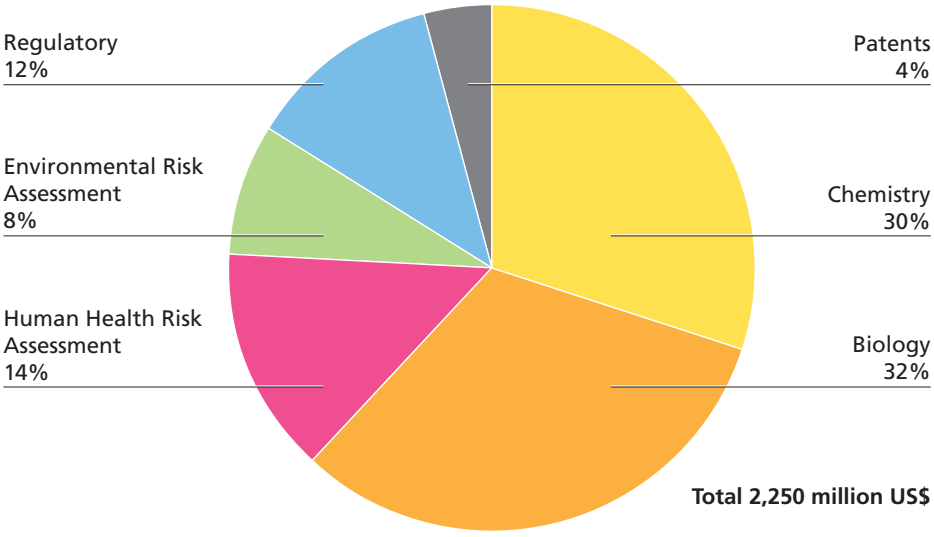
Source: Nomisma elaborations on Phillips McDougall (2007).

TABLE 6 I **AGROCHEMICAL INDUSTRY R&D EXPENDITURE SPLIT BY R&D PHASE (2004)**

R&D ACTIVITY	EXPENDITURE (US$ M)	% OF TOTAL
Discovery	705.2	31.3
New Product Development	506.8	22.5
Costs of managing existing business, excluding re-registration	558.7	24.8
Re-registration	397.2	17.7
Patents	82.1	3.7
TOTAL	**2,250.0**	**100.0**

Source: Nomisma elaborations on Phillips McDougall (2005).

FIGURE 4 I **AGROCHEMICAL INDUSTRY R&D EXPENDITURE (2004) BY SCIENTIFIC DISCIPLINE AND ACTIVITY**



Source: Nomisma elaborations on data from Phillips McDougall.

State level, yet national registration systems in some cases are also becoming more rigorous. Inconsistencies in approval between Member States could result in farmers in one country not having access to products that are available to farmers in a neighbouring country. For example, in 2006 a new system for the evaluation and registration of PPPs was introduced in France, with the evaluation of such products transferred to AFSSA (Agence Française de Sécurité Sanitaire des Aliments).

Meanwhile, the registration of generic products in the USA is becoming cheaper which will result in intensified competition in this market. This has led to more generic products registered in the market without increasing the opportunities for registration of new innovative products. The more restrictive political and regulatory framework in Europe compared with that of major competitors in the USA, Japan and China has led several of the large multinational companies to invest in research facilities in these countries as well as in India and Argentina – thus undermining the innovation potential and competitiveness of the R&D base of the agrochemical industry in Europe. Furthermore, the fact that some national authorities have tended to put a priority on generics registration has created disadvantages for new products, which have experienced significant delays in receiving authorisation. For example, last year in Spain more than 90% of the registrations were for generic products, while some new products have been waiting for registration for as long as four years.

CONCLUSIONS

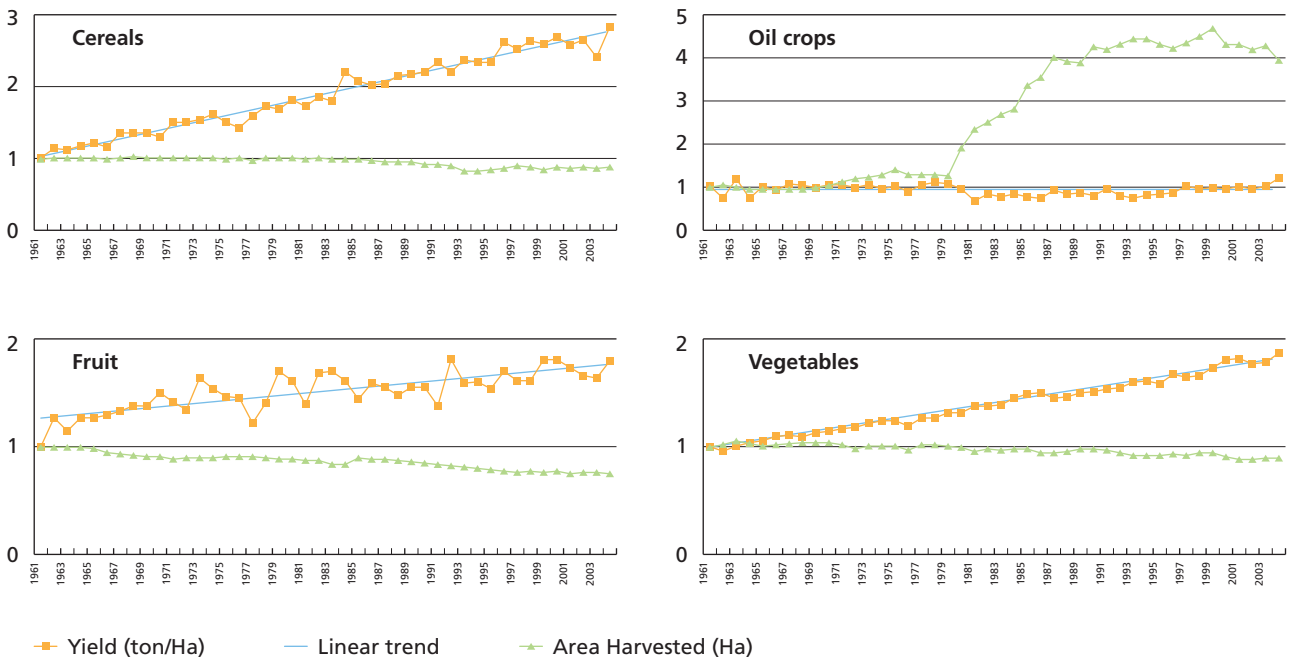
The crop protection industry is an important contributor to the European capacity for innovation and research and development. Yet the high cost of compliance with the regulations on plant protection products has created difficult conditions for the industry. In a phase in which many products subject to review are being withdrawn from the market, due to the application of Directive 91/414/EEC, research and development activities become even more essential in guaranteeing an adequate modernisation, effectiveness and safety of the European PPP portfolio. However, to maintain the current high levels of R&D and innovation capacity, the industry must be guaranteed an adequate return on the investment – already the R&D base with regard to PPPs for minor crops has been eroded, due to the high cost of discovery, development and registration coupled with lengthened registration times and uncertainties in review processes. More rigid regulations on PPP market access are likely to have an impact not only on the major R&D based companies, but also other firms that produce and market agrochemicals or that provide outsourcing services to the major companies.

3 INNOVATION WITHIN EUROPEAN AGRICULTURE

The focus of technology development in agriculture in the last half of the 20th century was to increase farm production efficiency, which was driven by innovations in machinery, plant protection products, fertilizers, information technologies, and plant breeding. While this approach was supply driven, consumers also benefited from increased production and low prices. The choice of technologies available to farmers was largely determined by the need to increase production, profits and productivity, while the main constraints on technology adoption included the availability of capital, knowledge of how to use the technology and market risks, which in the European Union were largely shielded by the CAP.

In the past, therefore, "good policy practices" were rather straightforward, relating primarily to increasing output, and the aim of agricultural policies was to increase productivity in agriculture. The strong CAP support provided by the EU during the last 50 years led to an extraordinary increase in overall agricultural production. However, the increase in output was not due to an expansion of the utilized area. As is seen in figure 5, historically the growth in production volume for all major crops, apart from oil crops, has come from increased yield resulting from improved varieties, better farming practices and knowledge, and the application of new technologies.

FIGURE 5 | **EU-15 MAIN CROP YIELDS AND AREA HARVESTED** (INDEX, 1961 = 1)



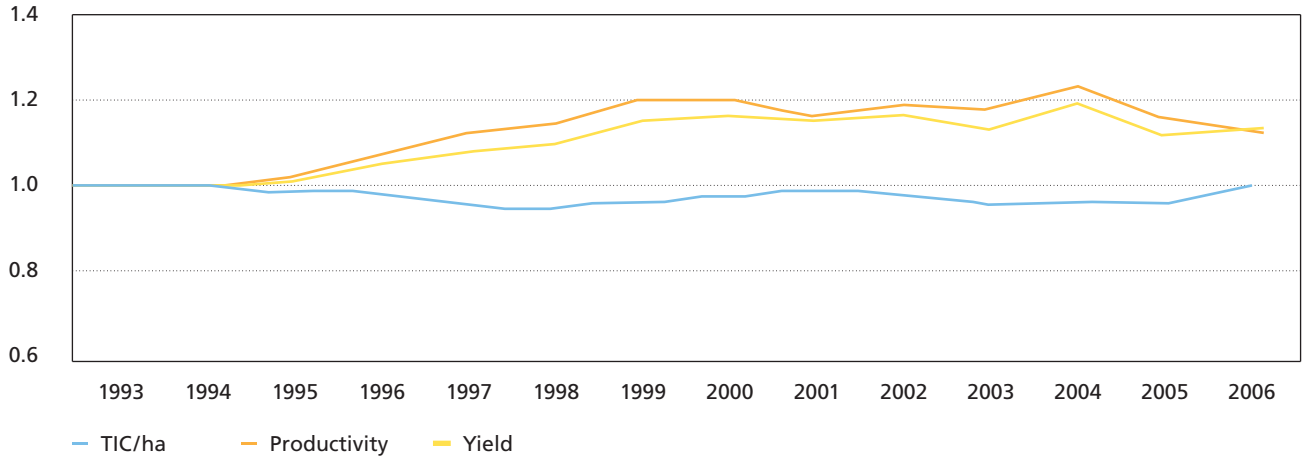
Source: Nomisma elaborations on FAOSTAT data.

Agricultural productivity rises when more output is produced with the same means of production and/or by economising on the production factors. In the past, the emphasis was placed mainly on achieving more physical returns per hectare or per animal by using more productive initial inputs, better feed conversion, more manure, and new and more effective agrochemicals, etc. Partly in

response to growing concern over environmental impact, over the past few years there has been a reduction in this trend in some countries: the focus has now shifted towards economising on inputs.

Figure 6 shows how average farm yield in the EU-15 has changed over the last 14 years: following a slight increase in the second part of the 1990s, overall production per hectare has tended to stabilize. During the same period, the level of intermediate inputs (fertilizers, plant protection products, seeds, energy and lubricants, etc.) used per hectare in crop and animal production has slowly decreased. Hence, the productivity of intermediate inputs in EU-15 agriculture, measured in terms of the ratio of output to inputs, has increased by nearly 1% per year since 1993 (+2% for France, Spain, Germany, Italy and UK together). On the other hand, in the 12 New Member States, a steady increase in the intermediate input consumption per hectare (+19%), denoting a progressive shift from subsistence agriculture to a more intensive model, has led to a substantial rise in the level of productivity (+8%) since 2000, contributing to strong growth in the average agricultural yield (+29%).

FIGURE 6 | **EU-15: AGRICULTURAL YIELD, INTERMEDIATE INPUT EMPLOYED PER HECTARE* (TIC) AND FACTOR PRODUCTIVITY°** (INDEX, 1993 = 1)



*Total intermediate consumption (TIC) = Value of total intermediate consumption per ha (UAA).

*ration between agricultural output and total intermediate consumption (Value).

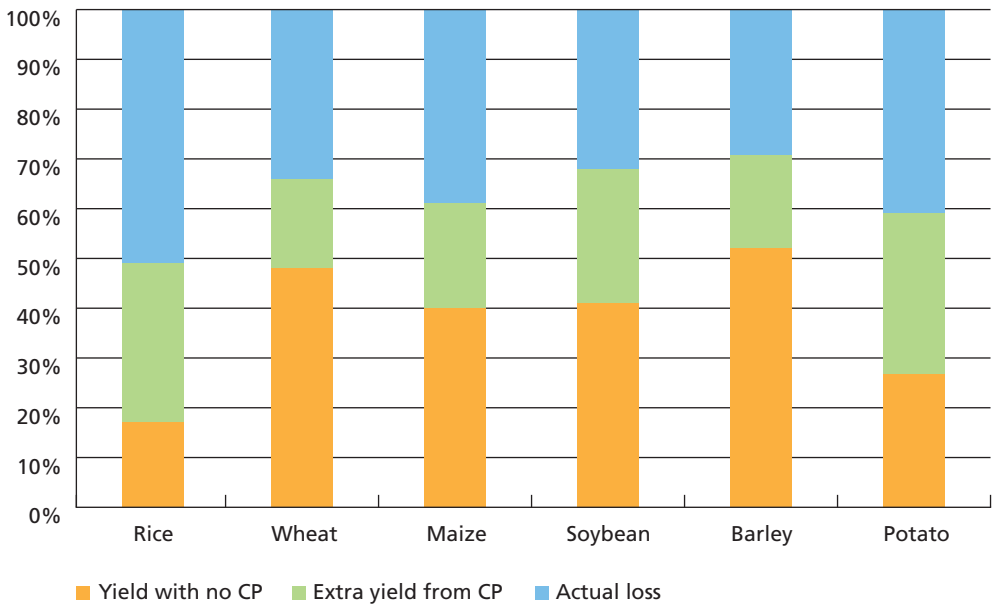
Source: Nomisma elaborations on Eurostat data.

Further evidence of agricultural productivity trends comes from a study by Leetmaa, et al. (2000), which estimates growth rates for Total Factor Productivity (TFP) indices in the EU-15, breaking down the indices into their components: efficiency and technical change. Efficiency relates to the use of existing inputs, while technical change embraces many potential sources of productivity growth, including improved seeds, better management techniques, new crop rotation sequences, etc. This survey revealed that in EU-15 agriculture (mainly in the northern countries) technical change has been a more important driver of Total Factor Productivity (TFP) growth than efficiency. The results of the study probably mainly reflect the effects of the 1992 Mac Sharry Reform of the CAP and partially those resulting from Agenda 2000. The progressive reduction of price supports and market protection, indeed, has led to some disincentives for continued intensive use of many agricultural input factors.

Since 1965, intensive (chemical) crop protection practices were able to nearly completely counteract the rising risks of potential losses due to reduced crop rotation, increased fertilizer use and high-yielding varieties that are often more susceptible to pests. The high damage potential of pathogens, animal pests and weeds could only be controlled by an adequate intensification of crop protection (CP), i.e. the use of varieties resistant/tolerant to pests, crop rotation, mechanical, biological and chemical controls. Figure 7 shows the relative contributions of different crop protection measures (chemical, biological and mechanical) in reducing losses in six different cash crops. The efficiency of pest control in maintaining crop yields is the highest in crops like potatoes and rice, for which 32% and 31%, respectively, of potential losses can be prevented.

In the overall context of crop protection practices, plant protection products (PPPs) play a critical role. When analyzing the partial productivity of PPPs (the relationship between a measure of output and an individual measure of input), it can be observed that the value of this indicator has risen over time, even though at a very slow rate (0.3% per year 1993–2006). However, this quantitative indicator does not adequately reflect the changes that have characterized the nature and the modes of use of PPPs. Over the course of time, in fact, innovation has made new PPPs available that present characteristics (toxicity, persistence in the environment, leaching potential, etc.) that increasingly respect the new legislative requirements regarding human and animal health and the environment.

FIGURE 7 I **CROP YIELD LOSS WITH AND WITHOUT CROP PROTECTION – CP (% IN ATTAINABLE YIELD)**



Source: Nomisma elaborations on Oerke et al. (1994, revised in 2004).

4 ROLE OF PLANT PROTECTION PRODUCTS IN EUROPEAN AGRICULTURE

OBJECTIVE

This chapter focuses on the quantitative analysis that was undertaken in order to estimate the possible impact that the proposed new regulation on the placing on the market of PPPs could have on the agricultural production system and thus on the Agri-food sector. This is the core of the study and also its most complex element.

The main criticality is presented by the tremendous variability that characterizes agricultural production in Europe. For this reason it was decided to analyze several case studies that could furnish some useful results that can be qualitatively generalized for agriculture as a whole. The three crops selected are wheat, a crop of great importance throughout Europe, the potato and the wine grape, which are products representative of central and northern Europe and the Mediterranean area, respectively.

For each crop, we have identified potential development trends within the forecasted period 2012–2020, estimating dynamics related to yields, cultivated surface area, production, domestic consumption and the trade balance.

Applying an original methodology for scenario analysis, these trends for conventional agriculture are then compared with the trends resulting from a hypothetical case of complete conversion of European agriculture to organic farming practices, production systems which currently use the least amount of PPPs in Europe. Thus we have been able to define two extreme cases:

- Conventional agriculture: scenario which corresponds to an unchanged legislative framework under which the availability of agrochemicals is similar to the current level;
- Organic farming: scenario in which the availability of plant protection products is minimal (even though not equal to zero, since also organic farming utilizes some PPPs, and even they are subject to the process of revision of Dir. 92/414/EEC and any future changes).

The analysis that follows is aimed at defining intermediate scenarios between the two extreme cases (maintenance of the status quo and the nearly complete elimination of PPPs) that will reflect the situation in which European agriculture could find itself as a result of the application of Dir. 91/414/EEC and the new proposal that is currently under discussion.

METHODOLOGY

In order to estimate the contribution of PPPs to the agronomic and economic performance of EU agriculture, three case studies were undertaken at the EU level, each one focussing on a different crop (wheat, potato and wine grape) which is considered to be important within EU agriculture.

The agronomic and economic performance of these three crops at the EU level was analysed by following a case study approach and focusing on the following Member States: France, Germany, Hungary, Italy, Poland, Spain and the UK. The selection of the above Member States was aimed at providing a fairly representative spectrum of the high variability within the EU of crop yields, modes of production, level of technology use, the yield potential and any limitations on further development of the selected crops.

For each of the three crops, the analysis takes into consideration the following:

- For the Member States covered by the study, the analysis examined trends in agronomic performance (in terms of yields) over the past decade, as well as made projections for yields through 2020, in particular:
  - The yields of each crop from 1995 to 2006 were calculated on the basis of Eurostat data.
  - Following a hypothesis of invariance from the present legislative framework on PPPs, the analysis calculated foreseeable changes in yields over the medium to long-term time horizon (2012–2020) on the basis of trends observed during the period 1995–2006 and by projecting linear trends for the period 2006–2020.

- For each Member State covered by the study, the yields from organic farming were compared with those from conventional farming on the basis of available data and information (scientific literature and bibliography). The aim of this analysis was to provide for each crop a coefficient for the reduction in yield (related to organic practices) to apply to the elaborations used in the scenario analysis.

On the basis of such data on yields, the ex ante impact assessment analysis was further developed by using a scenario approach. Thus, the foreseeable evolution of yields over the medium to long-term time horizon (2012–2020) was further elaborated in order to analyse the impacts of different hypotheses of "levels of change" in the regulatory framework for PPPs.

In particular, in this context, four different scenarios were considered:

- The "reference scenario" or "scenario 0", representing the foreseeable situation of the EU agricultural system under a medium-to-long term time horizon (2012–2020), following the hypothesis that no significant changes would occur in the regulatory framework for PPPs. Reference yield = Yc (yields of conventional farming).
- The "Radical scenario" or "scenario 3", the counterpoint to "scenario 0", was identified as a hypothetical situation in which all EU agriculture is "organic" (application of the agrochemical regulatory framework presently used for organic agriculture to the entire EU agricultural production). Reference yield = Yo (yields of organic farming).
- "Scenario 1" was identified as an intermediate scenario in which the EU agricultural system would experience minor impacts due to the changes in the regulatory framework for PPPs. Reference yield = Yo+[(Yc–Yo)*2/3].
- "Scenario 2" was identified as an intermediate scenario in which the EU agriculture system would experience major impacts by the changes in the regulatory framework for PPPs. Reference yield = Yo+[(Yc–Yo)*1/3].

This differentiation has allowed comparing the "reference scenario" to a number of different scenarios, each characterised by a different "level of availability of PPPs" and a consequent different "level of changes" in crop productivity and economic performance.

From the results obtained for the different crops, a summary of each scenario was elaborated, using a number of indicators (yields, area, production quantity, production value, domestic use, trade balance and level of self sufficiency) which were calculated at the EU level:

- The yields for each crop from 2002 to 2006 were calculated on the basis of Eurostat data; Following the hypothesis of invariance of the present legislative framework on PPPs, the foreseeable change in yields over the medium to long-term time horizon (2012–2020) was calculated on the basis of trends observed during the period 1995–2006 and by projecting linear trends for the period 2006–2020[1].

  Since there is high variability of yields from year to year, for each scenario the crop yields were calculated by taking into account the yield trends during the three years prior to the year considered:
  - Present situation, 2006 yield: average of yields for 2004–2005–2006;
  - Scenario 0, scenario 1, scenario 2 and scenario 3: yield 2012: average yields 2010–2011–2012; yield 2020: average yields 2018–2019–2020;
- For the present situation, the cultivated area of each crop was calculated as the average area for 2003–2006 on the basis of Eurostat data; the estimated changes in the cultivated areas

1 In the case of the analysis of the EU-27 the foreseeable evolution of yields was calculated on the basis of the average trend observed during the period 1995–2006 for the case studies, projecting the linear trend for the period 2006–2020.

of each crop over the medium to long-term time horizon (2012–2020) were calculated on the basis of the trends observed during the period 2000–2006 by projecting the logarithmic trend for the period 2006–2020[2].

For each scenario, the cultivated areas of each crop were calculated by taking into account the trends in cultivated area during the three years before the year considered[3].

- The production quantity of each crop was calculated on the basis of cultivated areas[4] and yields. The same method was utilised to estimate the foreseeable evolution of production over the medium to long-term time horizon (2012–2020) and in each scenario.
- The production value of each crop was calculated on the basis of the average unit value during the last three years (2004–2006). Such data were utilised both for the present situation and to estimate the foreseeable evolution of production value over the medium to long-term time horizon (2012–2020), resulting in a production value at constant prices.
- The domestic consumption of each crop was calculated as the average over the last three years on the basis of Eurostat data; the foreseeable evolution of domestic consumption of each crop over the medium to long-term time horizon (2012–2020) was calculated on the basis of the trend observed during the period 2000–2006 by projecting it forward for the period 2006–2020.
- The trade balance is calculated as the difference between exports and imports.
  - For the present situation, exports and imports were calculated as the average for the last three years on the basis of Eurostat data;
  - Over the medium to long-term time horizon (2012–2020), exports were calculated on the basis of the trend observed during the period 1999–2006[5], projecting it forward for the period 2006–2020; imports were calculated using the equilibrium formula:
    imports = Consumption + Exports – Production.
- The level of self sufficiency is the ratio of production over consumption.

The analysis according to the scenarios has led to a set of different situations (defined by the value of different indicators selected) for the medium (2012) and long (2020) timeframes. The objective of the study was to identify, from among the different situations that were outlined, the one which could most realistically reflect for each case study the new conditions that could emerge, depending on the different availabilities of PPPs due to changes in the current normative framework.

Toward this purpose, three focus groups were set up (one for each case study), comprising different experts from the PPP industry. These experts evaluated the possible impacts of the new regulations on the principal groups of active substances used on the three crops examined (wheat, potato and wine grape) and the relative effect on production performance, identifying the scenario that is most probable in a 2012 and 2020 perspective. Finally, in addition to the three case studies, an evaluation of the cereals branch as a whole was undertaken, which followed the same methodology defined for the individual crops.

2 In the case of potatoes in the EU-27, the foreseeable change in cultivated area was calculated separately for Poland (on the basis of the trend observed during the period 2002–2006) and other EU-27 countries (trend observed during the period 2000–2006). In Poland, the area cultivated with potatoes has considerably decreased during the past decade, decreasing from 1.5 million hectares in 1995 to only about 0.8 million hectares in 2002 (–47%), while the trend over the last period shows a slower decrease.

3 In the case of the EU-27, the area was calculated as the sum of the areas of the individual countries. In the case of missing precise data, the average of the following three years or preceding three years was used.

4 Data on the areas of production also comprise organic cultivation areas. However, according to Eurostat data, the areas of organic production are not significant compared to the total cultivation areas of the crops under study:
Wheat: the share of organic area compared to the conventional area is 4.8% in Italy (2005) and 1% in the UK (2005);
Potatoes: the share of organic area compared to the conventional cultivation area is 0.3% in France (1998), 1.1% in Italy (average 1999–2005), 0.2% in Hungary (average 2002–2004) and 1.3 % in the UK (average 2003–2006);
Wine grape: the share of organic area as compared to the conventional cultivation area is 1% in Spain (average 1998–2005), 1.7% in France (average 1998–2005), 4.3% in Italy (average 1998–2005) and 0.5% in Hungary (average 2002–2004).

5 Previous years' data are not available for EU-27.

WHEAT

WHEAT PRODUCTION

In 2006, the EU-27 was the world leader in wheat production, accounting for nearly 21% of the world output (604 million tons). Historically, wheat has been one of the main cultivated crops in the EU, presently representing 13.7% of the total EU-27 utilized agricultural area (UAA) and 43% of the total cereal area.

TABLE 7 | **EU-27 WHEAT AREA AND PRODUCTION (2006)**

	Total area		Total production	
	Mil. ha	Var. 00–06	Bil. €	Var. 00–06
Wheat	24.8	–6.9%	18.2	–12.6%
Cereals	57.4	–6.4%	39.9	–7.0%
Crops (total UAA)	181.6	–18.8%	142.2	–3.4%
Wheat share of total cereals	43.3%		45.7%	
Wheat share of total crops	13.7%		12.8%	

Source: Nomisma elaborations on Eurostat data.

As a result of the overall impact of the Mac Sharry and Agenda 2000 Reforms, which introduced decoupling and set-aside quotas, the total area cultivated with wheat decreased, though at a lower rate compared to cereals. Furthermore, it is interesting to note that more than half of the total wheat area throughout Europe is located in six countries: France first, followed by Germany, Poland, Romania, Spain and UK. In terms of the quantity harvested, in 2006 the EU-27, thanks to its high-yield capacity, was able to produce 126 million tonnes. Overall production has slightly decreased since 2000, but this trend doesn't reflect the real situation, since this decline (also regarding cultivated land) mainly concerns the EU-15. As a matter of fact, most of the 12 NMS increased their wheat areas and output (Hungary +20%, Estonia +50%, etc.). In any case, wheat still plays a key role in EU-27 agriculture, representing 45.7% (of the value) of the cereal output and 12.8% of overall agricultural crop production.

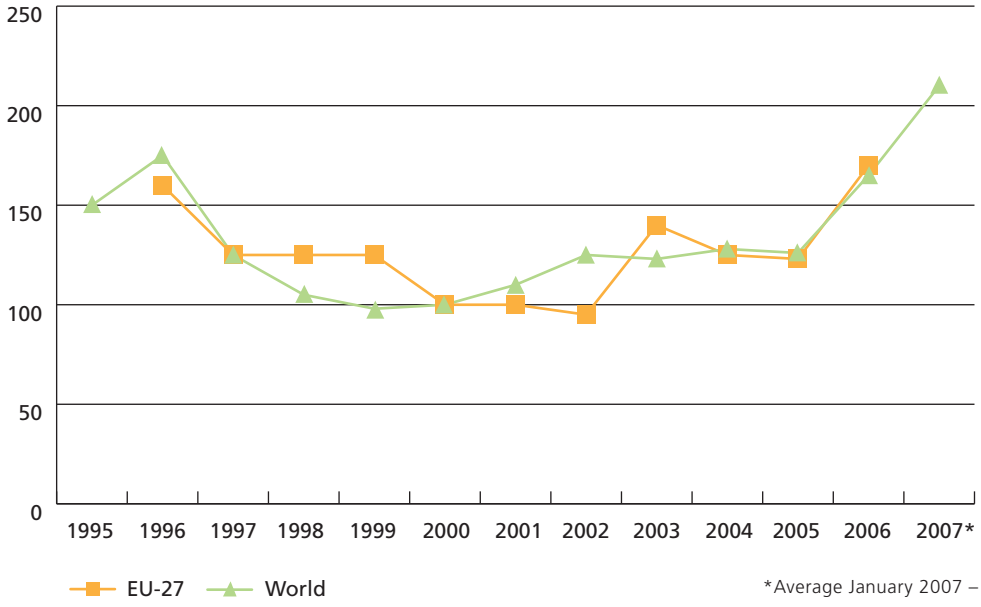
With regard to world wheat production, in 2006 China was the second largest global wheat producer, accounting for 17% of the total output and followed by India, USA, Russia and Canada. However, world wheat production patterns are progressively changing, due to economic-political developments and varying factor endowments; while in the EU-27 and the USA wheat production slightly declined over the last 5 years, other countries started exploiting their lands more intensively, increasing their output (i.e. Russian Federation, +30%; China, +4.8%). As seen in the following figure, after the 1996 peak due to the world cereal crisis, a general reduction in world and EU-27 wheat prices occurred at the end of the 1990s – this reduction in the price level was mainly due to the cuts in support prices resulting from the CAP reforms since 1992. Later, the prices started to rise again, reaching even higher levels in 2007 than in 1996.

A sharp drop in world wheat production in 2006, driven by lower output in nearly all major exporting countries, resulted in one of the periods with the tightest world supply and demand for wheat in more than two decades. While international wheat prices continued on an upward trend during 2006, the price increase accelerated as production prospects deteriorated, especially in several wheat-exporting countries (figure 8). The decline of wheat crops in major producing countries in the Southern hemisphere (especially drought-devastated Australia) and limited exports from Ukraine added further strength to prices. Rising world prices have boosted sales from the European Union, despite a strong Euro and in the absence of export refunds. The production shortfalls in 2006 in many parts of the world resulted in a large drawdown of world wheat inventories

to their lowest levels since the early 1980s. The most significant reductions occurred in the major exporters, namely the United States, Australia, the European Union, Canada and Ukraine.

Finally, even though so far the EU-27 has showed a positive level of self-sufficiency (expressed through the production-consumption ratio), trade in wheat still plays an important role, since overall trade flows represent about 13% of the level of domestic wheat production. Consequently, a possible drop in the internal supply (i.e. due to changes in production patterns, adverse climatic conditions, pest attacks, etc.) would require higher imports from countries such as Canada, USA, Ukraine and Australia, which are the main EU-27 partners in wheat trade.

FIGURE 8 | **EU-27 AVERAGE WHEAT PRICE INDEX (2000 = 100)**



*Average January 2007 – October 2007.

Source: Nomisma elaborations on FAPRI and UNCTAD data.

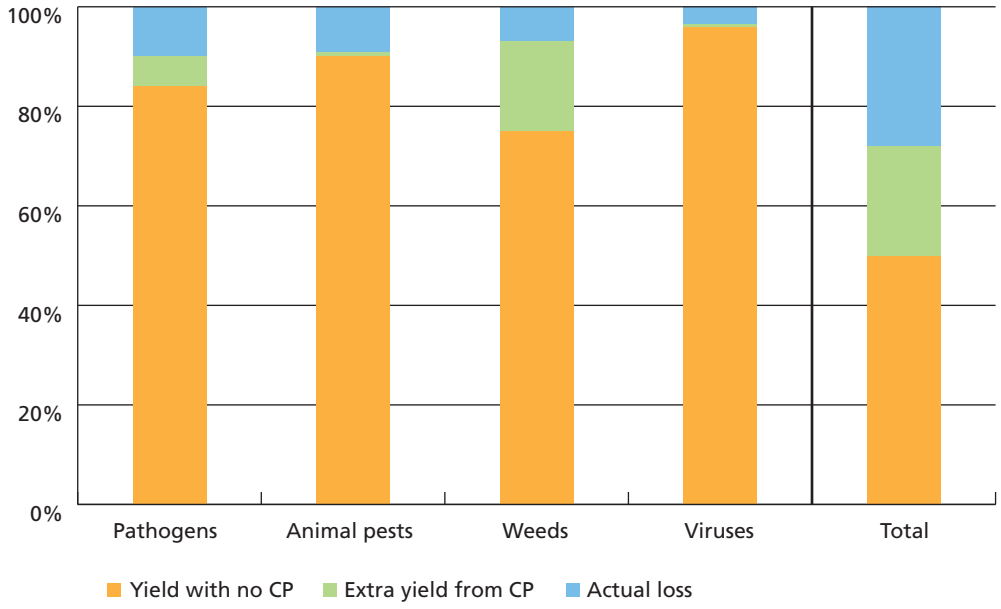
WHEAT PESTS' IMPACT ON YIELDS AND THE ROLE OF ORGANIC FARMING

Agricultural systems are not 'natural', undisturbed ecosystems, and the inherent control mechanisms are often not sufficient to safeguard high crop productivity. Farmers have to cope with the competition of other organisms whose survival is facilitated by the uniformity and repeated cultivation of susceptible crops, endangering productivity. In order to promote crop growth and yield, farmers have to protect plants against pests, organisms that damage crops grown for human consumption. In addition, the ultimate goal of crop protection is not the elimination of pests, but the minimization of crop losses to an economically acceptable level.

Oerke, et al. (1994) published a global estimate of losses for eight major food and cash crops, including rice, wheat, maize, potatoes, cotton, soybean, barley, and coffee. Crop losses in wheat estimated by Oerke in 1994 (the results of this study were updated in 2004) show that weeds are the most important contributor to wheat yield loss. Fungal diseases (especially Septoria, Rust and Buleria Graminis) increase with agricultural intensity (use of nitrogen, limited crop rotation and so forth). Oerke stated that in Western Europe, weeds and fungal diseases have a comparable effect on wheat productivity.

The relevance of crop protection practices (mechanical, biological and chemical) is clearly illustrated by their overall estimated effects on wheat yield, as shown in figure 9.

FIGURE 9 I **IMPORTANCE OF CROP PROTECTION IN WHEAT (% YIELD COMPOSITION)**



Source: Nomisma elaborations on Oerke et al. (1994, revised in 2004).

BOX 3 I **YIELDS OF ORGANIC WHEAT COMPARED TO CONVENTIONAL WHEAT**

COUNTRY	YIELDS OF ORGANIC WHAET COMPARED TO CONVERNTIONAL WHEAT	SOURCE
Germany	65%	Mader et al. (2002)
Spain	65%	Mader et al. (2002)
France	75%	INRA (2003)
Italy	64%	Elaboration on Eurostat data
United Kingdom	60%	Jackson and Lampkin (2006)
Hungary	65%	Mader et al. (2002)
Poland	65%	Mader et al. (2002)

Source: Nomisma – Areté elaborations.

In order to empirically determine the contribution of plant protection products to yield, the yields from organic farming were compared with those from conventional farming on the basis of available data and information (scientific literature and bibliography). From this analysis it is possible to obtain for each crop a coefficient associated with the reduction in yield related to organic practices that can be applied to the elaborations used in the scenario analysis.

When observing the differences, in terms of yields, of conventional wheat compared to organic wheat (box 3), the available bibliography shows that cereal crop yields under organic management in Europe typically are 60% to 70% of those under conventional management[6].

There are differences in the yield losses reported by Oerke et al. (figure 9) and the various studies on organic farming (box 3), due to the fact that the Oerke et. al study covers worldwide agriculture, whereas the other studies focus only on Europe. However, despite different national agricultural conditions, for many of the countries studied these results are fairly similar.

WHEAT SCENARIO ANALYSIS

As seen previously, crop protection plays quite an important role in controlling pest damage, hence substantially affecting the final crop yield and overall production. A possible change in the regulatory framework towards the elimination or partial replacement of some ASs could seriously reduce the number of tools that farmers can use to protect their crops.

At the moment it is not possible to evaluate the precise impacts that the changes to the regulation will have on wheat yields. However, as described in the methodology, this study aims to identify to what extent such changes could affect crop yields by defining a range within which it will be possible to predict the new (reduced) yields as consequence of the implementation of the new regulations. In particular, the yields used as references were the following:

- Conventional wheat yields, which were used in calculating the reference scenario (scenario 0), corresponding to a scenario without modification of the present regulation;
- Organic wheat yields (estimated as being, on average, 65% of conventional yields), which were used in calculating the radical scenario (scenario 3), corresponding to a scenario in which all PPPs would be prohibited (excluded from Annex I of Dir. 91/414/EEC).

As shown in the methodology, in addition to the calculations for these two extreme scenarios, yields for the two intermediate scenarios were also calculated (scenario 1: minor changes to the present regulation and scenario 2: major changes to the present regulation).

According to our evaluation, an increasing reduction in wheat yields would bring about a significant decrease in wheat production, with a consequent decline in the EU level of self-sufficiency in wheat (table 8). The data associated with scenario 1 show a reduction in wheat production of about 13% in 2012 and 8% in 2020 and, at the same time, a reduction in the level of self-sufficiency both for the medium and for the long-term period. Data associated with scenario 2 show similar levels of reduction in self-sufficiency over the medium (77%) and long term periods (76%). As a consequence of eroded self-sufficiency, an increased dependence on imported wheat is expected: data show that the trade balance, which was positive in 2006 (+4 million tons), would become increasingly negative: for scenario 1 –15.6 million tons in 2012 and –17.2 million tons in 2020, for scenario 2 – 31.2/33.6 million tons and for scenario 3 and –46.7/–49.9 million tons.

6 The reference study for the assessment of the yield of organic wheat was a 21-year study of agronomic and ecological performance of biodynamic, bioorganic, and conventional farming systems in Central Europe, carried out by the Swiss organic farming association (Mader at al., 2002). Additional studies utilised to estimate the yields of organic wheat in France and in the UK were: INRA (2003) and Jackson and Lampkin (2006), see bibliography.

TABLE 8 I **WHEAT: SCENARIO ANALYSIS (2012–2020)**

	2006	2012				2020			
INDICATOR	**Present situation**	**Scenario 0 (reference scenario)**	**1**	**2**	**3 (radical scenario)**	**Scenario 0 (reference scenario)**	**1**	**2**	**3 (radical scenario)**
Yield (t/ha)	5.3	5.3	4.7	4.1	3.5	5.7	5.0	4.3	3.7
Area (000 ha)	25,669	24,980	24,980	24,980	24,980	24,746	24,746	24,746	24,746
Production (000 t)	135,066	133,370	117,810	102,250	86,691	140,057	123,717	107,377	91,037
Value (mln €)	19,506	19,261	17,014	14,767	12,520	20,227	17,867	15,507	13,148
Domestic use (000 t)	130,195	133,404	133,404	133,404	133,404	140,948	140,948	140,948	140,948
Export (000 t)	11,082	11,651	11,651	11,651	11,651	11,613	11,613	11,613	11,613
Import (000 t)	6,558	11,685	27,245	42,805	58,365	12,504	28,844	45,184	61,524
Trade Balance (000 t)	4,558	–34	–15,594	–31,154	–46,713	–891	–17,231	–33,571	–49,911
Degree of self sufficiency	104%	100%	88%	77%	65%	99%	88%	76%	65%
Variation on 2006 production		–1%	–13%	–24%	–36%	4%	–8%	–21%	–33%

*Change % 2000/2005. Source: Nomisma elaboration on FAPRI and FAO Data.

THE IMPACT OF THE NEW REGULATION ON WHEAT PRODUCTION

After calculating the estimated changes in wheat yield and production under the different scenarios and analyzing the contribution of crop protection in controlling different pests, a focus group tried to define the overall effects of the new regulation. In other words, a specialised group of agrochemical industry experts participated in formulating forecasts of possible results from the application of Directive 91/414/EEC (2012 impact) and the new regulation that is currently being discussed (2020 impact).

Beginning with a detailed analysis of the specific requirements of the present regulatory framework (under Directive 91/414/EEC) and those foreseen under the new regulatory proposal, the group of experts assessed their impacts on the markets of each AS product line, also taking into consideration the rate of innovation in introducing new PPPs. By estimating which specific PPPs could be banned or substituted and by using the known results of their effects on crop yields, it was possible to calculate overall reductions in crop production levels. Consequently, the experts employed this technical evaluation methodology in order to identify the best-fitting and most likely scenarios among those that emerged from the survey. The selected scenarios function as different benchmarks in helping to position the most suitable forecasts.

With regard to wheat, the main estimated impacts of the new regulation are summarized in figure 10, in which experts highlight the most commonly used PPPs that will likely be affected by the changes in regulation.

After having identified the best-fitting scenario, we first provided estimates of one of the impacts resulting from the two different regulatory frameworks, without taking into consideration any future agricultural and economic trends. In other words, in order to isolate the direct impact of the directives (91/414/EEC and the new regulation), the variation in the yield (and production) level was computed and analyzed comparing the selected scenario with the reference scenario (conventional wheat yields) in both 2012 and 2020 (see figure 11). The evaluation shows that over the medium term (2012), the effects of the current regulatory framework will generate an impact in between those resulting under scenarios 2 and 3: as shown in figure 11, wheat yield in the

EU-27 could be reduced on average by 29%, declining from 5.3 t/ha. to 3.8 t/ha. With regard to the long-term outcomes of the new regulation modifying Directive 91/414/EEC (2020), forecasted results that lie between those from scenarios 2 and 3 are again considered probable: domestic wheat yield will be seriously affected as well, with a possible 29% reduction from 5.7 t/ha. to 4 t/ha (reflecting the same level of impact seen in the 2012 forecast).

In order to conduct a far more detailed assessment, we have taken into account other possible relevant variables. Thus, we identified potential development trends within the two forecasted periods, 2006–2012 and 2006–2020, by introducing variables to reflect dynamics related to yields, cultivated surface areas, production, domestic consumption and the trade balance. Incorporating these variables into the four different scenarios has permitted observing the likely effects of the PPP regulatory framework coupled with the future estimated trends for the above indicators.

FIGURE 10 | **WHEAT: IMPACT OF PPP REGULATION CHANGE**

PRODUCT LINE	ESTIMATED IMPACT ON WHEAT
Herbicides	New regulation that replaces 91/414 will affect sub market of pre emergence early post control. It is estimated that there will be a ban or strong reduction of dose rate for the most commonly used AS in Europe for pre and early post emergence control (belonging to chemical families of fenilureas fenoxy anilides and others). Remaining post emergence AS will not effectively control weed infestation, especially in Central and Northern Europe
Fungicides	It is estimated that very old fungicides, still effective and a key part of fungal diseases control in wheat, will be affected as well. If important AS belonging to chemical families of triazoles isophtalonitriles, morfolines and others) are reduced or banned two main effects are expected: reduction of control and increasing resistance
Insecticides	An insecticide class probably affected could be pyrethroids, base of effective and low cost control of aphids. Other important AS widely used in wheat, belonging organophosphate family, will probably disappear as well
Impacts between scenario 2 and 3 results in 2012 and between 2 and 3 results in 2020	

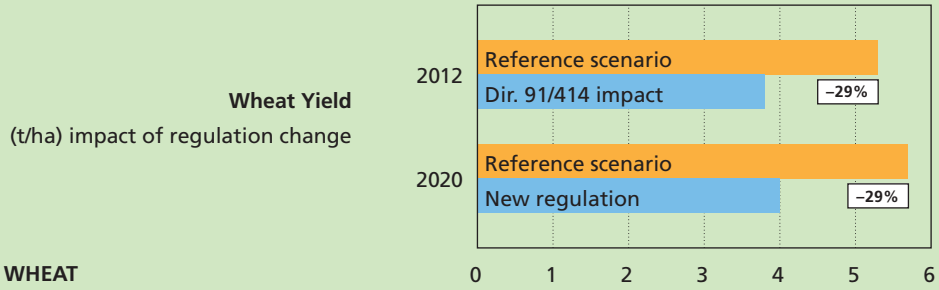
Source: Nomisma elaborations on Eurostat data.

In analyzing the dynamic impact of the two regulatory frameworks, the main findings for wheat show that over the medium term (2012) wheat production in the EU-27 could decrease by nearly 30%, further reducing the level of self-sufficiency (in this case to around 71%) and thus leading Member States to import larger quantities of wheat from extra-EU-27 countries (especially Canada, Australia, the Russian Federation, Ukraine and USA). As for the long-term impacts of the new regulation (2020), domestic wheat output would be seriously affected as well, with a possible 27% reduction and an even worse trade balance, reaching a nearly 41 million ton deficit compared with the 4 million ton trade surplus in 2006 (imports were at that time 30–40% of total domestic use). Such a deficit would be even further exacerbated by the expected increase in domestic wheat consumption over the period, while self-sufficiency remains around 70%. In sum, it could be observed that, even though the dynamic impact analysis took into consideration forecasted changes related to a larger number of indicators (area, consumption, trade, etc.), the final impact, both for 2012 and 2020, was more or less the same as in the initial assessment of direct impact – which, in fact, is quite relevant.

WHEAT PESTS AND THEIR EFFECT ON QUALITY

Most of the diseases, pests, disorders, or stresses that hit wheat crops can be economically significant for the farm balance sheet whenever they seriously compromise production yield. Yet these types of damage don't affect just the output quantity, but also the quality of the final product. Pests could directly or indirectly spoil the characteristics of the grain, hence also having consequences on the final product (i.e. flour). This is the reason why a good combination of crop protection techniques enables farmers to guarantee not only food security, but also food safety and quality. Box 4 shows how quality could be compromised in case wheat crops are hit by different pests.

FIGURE 11 | **DIRECT AND DYNAMIC IMPACT OF THE TWO REGULATORY FRAMEWORKS OVER THE MEDIUM TO LONG TERM (2012–2020)**



DYNAMIC IMPACT	PRODUCTION (MIL. T)	SELF SUFFIENCY
Present situation (2006)	135	104%
Dir. 91/414 (2012)	94	71%
Impact 2006–2012	–30%	–33%
New Regulation (2020)	99	70%
Impact 2006–2020	–27%	–34%

Source: Nomisma – Areté elaborations on Eurostat data.

BOX 4 | **MAIN WHEAT DISEASES AND PEST EFFECTS ON QUALITY**

Pathogens	Pathogens have strong effects on protein content, thus raising bakery technical issues. Flour standardization could be very difficult to manage since the quality varies significantly due to pest pressure. The whole flour, pasta and bakery food chain could be impacted. The presence of fungi like fusarium usually generates mycotoxins issues (some dedicated spray may reduce fusarium attacks, hence reducing mycotoxins in flour content).
Weeds	Direct competition for nutrients, water, and light is the main damage caused by weeds. The competition of weeds for nutrients will lead to less well developed plants and end up in an overall quality decrease (baking quality, protein content could be seriously affected). Weeds influence maturity development and often change the even maturity in a canopy (inhomogeneous maturity pattern in a field). Weeds increase the humidity in the cereal canopy and lead to higher disease infestation (see pathogen effects). Some weeds basically disable good harvesting practices and a lot of biological debris will end up in the harvested crop (this means expensive triage later, some of this debris is not healthy).
Animal pests	Animal pests damage to wheat is mainly due to aphids, which can prevent the ear from correctly filling the grains after the flowering stage. The consequences are low specific weight (lower density) as well as low protein content.

Source: Special Eurobarometer 276 (2007).

POTATO

POTATO PRODUCTION

For most of the 20th century, Europe was the world leader in potato production. Now Asia has become the world leader, but seven European countries are still among the top 10 global producers. The main producers in the EU-27 are five countries (Germany, Poland, France, the Netherlands and the United Kingdom) controlling nearly 70% of total EU production. The most important Mediterranean potato-producing country is Italy (contributing 3% of the total EU-27 output).

In addition, the EU-27 also has the highest level of potato consumption in the world (almost 100 kg per capita per year). Despite the fact that the area cultivated is just a small part of overall UAA, the potato is the most important crop (in terms of area and production value) compared to other vegetables and horticultural products (table 9).

TABLE 9 | **EU-27 POTATO AREA AND PRODUCTION (2006)**

	Total area		Total production	
	Mil. ha	Var. 00–06	Bil. €	Var. 00–06
Potato	2.2	–31.1%	6.4	–14.6%
Vegetables	4.5	–23.5%	29.3	–7.4%
Crops (total UAA)	181.6	–18.8%	142.2	–3.4%
Share potato in total vegetables	50.3%		21.8%	
Share potato in total crops	1.2%		4.5%	

Source: Nomisma elaborations on Eurostat data.

Analyzing the data in table 9, it immediately becomes evident that cultivated area and output have declined during the past few years in the EU-27 (–31.1%); however, it is important to read beneath this trend. While EU-15 areas and production slightly decreased, along with progressive growth in yield levels, the 12 New Members halved their cultivated areas and output. This situation is mainly due to the ongoing restructuring process of the potato market in Poland; whereas its production accounts for around 16% of the EU-27 output, a sharp reduction has occurred since 1995 (from 24 million tons to less than 9 million tons produced). In this country, particularly the reduction in cattle stock and the increasing competition of other inputs are substantially lessening the demand for potatoes for animal feed (as a percentage of total domestic uses, potatoes for animal feed are particularly important in Poland, where this kind of use accounts for 44% of potato consumption).

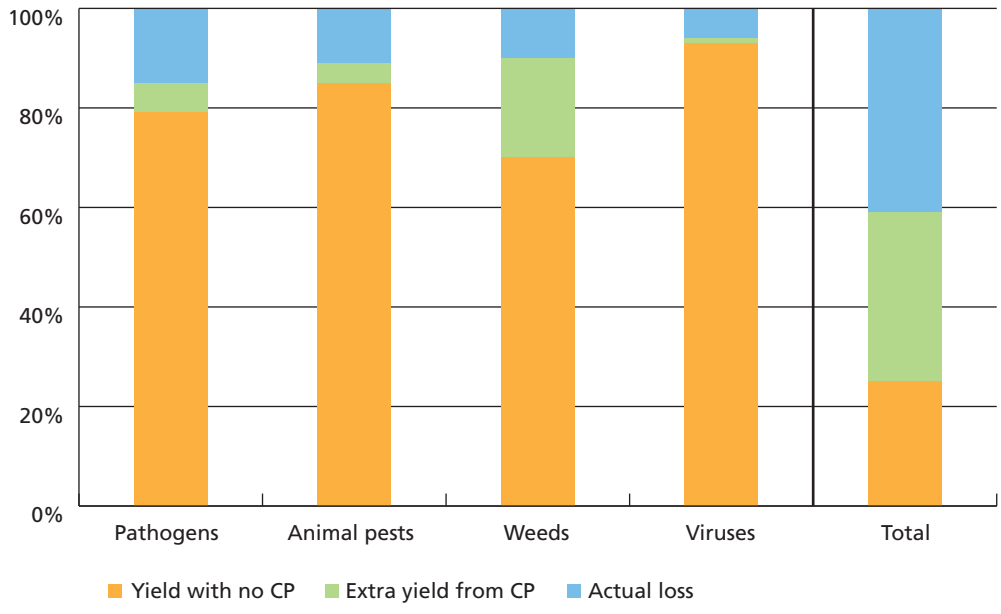
Potato production in Europe is not homogeneous because of specific agronomic, environmental and economic aspects that differentiate central and northern European from Mediterranean countries. Many Western European countries are shifting from potato growing to processing and production of seed tubers for export. In this context, the potato supply pattern is truly different in the Northern countries, where producer associations and their direct link with processors and the food chain are more developed than in the Mediterranean area. Furthermore, potatoes in northern Europe are mainly used for fresh consumption, but it must be taken into account that a significant share is delivered to the processing industry (20–30%). On the other hand, in Mediterranean countries, processing is less important and a higher relevance is given to fresh product quality standards (usually higher than in the north), thus with an impact on the final price. Regarding the price level in the EU-27, it is important to differentiate the EU-15 from the 12 NMS. While in the EU-15 the real producer prices have gradually moved downwards (due to lower production costs, higher competitiveness, falling demand for table potatoes, etc.), in some New Member States such as Poland, there has been a general increase in prices of main crop potatoes.

In 2006 China was the world leader in potato production with a 22% share, followed by the EU-27 (18%), the Russian Federation (12%) and India (7.6%). The world potato sector is undergoing major changes. Until the early 1990s, most potatoes were grown and consumed in Europe and North America. Since then, there has been a dramatic increase in potato production and demand in Asia (China +120%).

Potatoes are commonly regarded as a bulky, perishable, and high transport cost commodity with limited export potential, confined mostly to cross-border transactions. As a matter of fact, EU-27 trade in fresh potatoes is just 2% of the overall domestic quantity produced. However, these constraints have not hampered the international potato trade, which has doubled in volume and risen almost four-fold in value since the mid-1980s. This growth is due to unprecedented international demand for processed products, particularly frozen potato products. With regard to these processed products, thanks to its strong food industry, the EU-27 is still the world leader, accounting for more than 60% of world exports. In contrast, developing countries have not been beneficiaries of this trade expansion. As a group, they have emerged as leading net importers of the commodity, but not of the processed product.

As long as consumers require much higher dietary, hygienic and health standards and processors need low cost materials that fit changing consumer requirements, there is room for the development and the introduction of new varieties of potatoes offering better quality, higher yield and improved resistance to diseases. Therefore, the change in the demand for potatoes and the rise in world demand for processed potato products will provide an excellent opportunity for expanding the business of the EU breeders of seed potatoes – also taking into account the growing importance that the FAO is assigning to this crop (2008 will be the International Year of the Potato).

FIGURE 12 I **IMPORTANCE OF CROP PROTECTION IN POTATOES (% YIELD COMPOSITION)**



Source: Nomisma elaborations on Oerke et al. (1994, revised through 2004).

POTATO PESTS' IMPACT ON YIELDS AND THE ROLE OF ORGANIC FARMING

As vegetative propagation predominates in potato production, all pest groups are of high economic importance. The estimates for actual losses due to pathogens, viruses, animal pests and weeds worldwide are very important. Major pathogens, viruses and animal pests are widely distributed, resulting in low variation of total loss rates among regions. The relevance of potato protection practices is shown in figure 12.

According to the available bibliography (box 5), in potato production, the reduction in yield due to the use of organic farming methods may be estimated as being around 48%[7].

POTATO SCENARIO ANALYSIS

As in the case of wheat, since it was not possible to estimate the direct impact of the changes in the PPP regulatory framework on potato yields, the future scenarios were calculated by estimating the range of possible new (reduced) yields foreseen as a consequence of the implementation of the new regulations (table 10).

Indeed, the new yields will probably range between conventional potato yields (scenario 0) and organic potato yields (scenario 3), which in our evaluation have been used to represent the extreme scenarios. It may be assumed that, as a result of the change in the PPP regulatory framework, potato farming would experience a reduction in yields at a level within this range. In particular, depending on the overall variable projections, the decrease in production is estimated as ranging from 49% (scenario 3) to 14% (scenario 0) over the medium term and from 55% (scenario 3) to 25% (scenario 0) over the long term.

BOX 5 | **YIELDS OF ORGANIC POTATOES COMPARED TO CONVENTIONAL POTATOES**

COUNTRY	YIELDS OF ORGANIC POTATOES COMPARED TO CONVENTIONAL POTATOES	SOURCE
Germany	62%	Mader et al. (2002)
Spain	62%	Mader et al. (2002)
France	51%	La filière Pomme de Terre BIO – CNIPT – ONIFLHOR, AND-international
Italy	62%	Average
United Kingdom	62%	Jackson and Lampkin (2006)
Hungary	62%	Mader et al. (2002)
Poland	62%	Mader et al. (2002)

Source: Nomisma – Areté elaborations.

The level of self-sufficiency would decrease to a similar extent: while in 2006 the EU was self-sufficient in potatoes (105%), data show an increasing dependence on imported products, both over the medium and the long term. Data regarding scenario 1 show a level of self-sufficiency in potatoes of 87% over the medium term and of 80% over the long term, with a negative trade balance of –7.3 million and –10.6 million tons, respectively. Data associated with scenario 2 and scenario 3 show an additional increase in imported products and an additional reduction of the level of self-sufficiency, which is estimated to be about 60%–73% in 2012 and about 55%–68% in 2020.

7 The reduction of yields was calculated by using as main reference the study of Mader at al. (2002): according to this study, potato yields in the organic systems were 58–66% of those in the conventional systems.

TABLE 10 | **POTATO: SCENARIO ANALYSIS (2012–2020)**

	2006	2012				2020			
INDICATOR	**Present situation**	**Scenario 0 (reference scenario)**	**1**	**2**	**3 (radical scenario)**	**Scenario 0 (reference scenario)**	**1**	**2**	**3 (radical scenario)**
Yield (t/ha)	27.0	29.3	25.4	21.5	17.6	32.7	28.3	24.0	19.6
Area (000 ha)	2,387	1,882	1,882	1,882	1,882	1,485	1,485	1,485	1,485
Production (000 t)	64,532	55,198	47,839	40,479	33,119	48,530	42,059	35,588	29,118
Value (min €)	6,905	5,906	5,119	4,331	3,544	5,193	4,500	3,808	3,116
Domestic use (000 t)	61,522	55,204	55,204	55,204	55,204	52,623	52,623	52,623	52,623
Export (000 t)	893	1,165	1,165	1,165	1,165	1,320	1,320	1,320	1,320
Import (000 t)	581	1,171	8,531	15,891	23,250	5,413	11,884	18,355	24,825
Trade Balance (000 t)	312	–6	–7,366	–14,726	–22,085	–4,093	–10,563	–17,034	–23,505
Degree of self sufficiency	105%	100%	87%	73%	60%	92%	80%	68%	55%
Variation on 2006 production		–14%	–26%	–37%	–49%	–25%	–35%	–45%	–55%

Source: Nomisma – Areté elaborations on Eurostat data.

THE IMPACT OF THE NEW REGULATION ON POTATO PRODUCTION

With regard to potato production, the main estimated impacts of the new regulation are summarized in figure 13, in which experts have indicated how the most commonly used PPPs will likely be affected by the change in regulation.

FIGURE 13 | **POTATO: IMPACT OF PPP REGULATION CHANGE**

PRODUCT LINE	ESTIMATED IMPACT ON POTATO
Herbicides	It can be expected that key AS for non selective control of weeds and desiccation of potato before harvesting will be significantly impacted by new regulation replacing 91/414. Taking into account that weed control in potatoes is based on AS included in the family of triazinones and few others, it can be concluded that potato growers will not have many alternatives in the future
Fungicides	Some important fungicides like acetamides, dithiocarbamates, morpholines would encounter difficulties in being reregistered under the new rules, reducing choice and alternatives for growers
Insecticides	insecticides for potatoes, pyrethroids and organophosphorates (widely diffused) will be significantly affected by new regulation replacing 91/414 with important consequences for insect control (e.g. Colorado Potato Beetle)
Impacts between scenario 1 and 2 results in 2012 and between 2 and 3 results in 2020	

Source: Nomisma elaborations on results from agrochemical experts focus group.

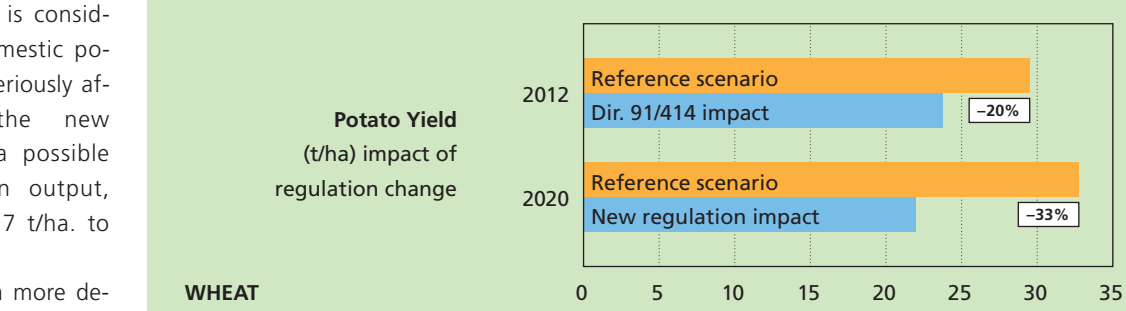
As was done for wheat, the variation in the yield (and production) level of potatoes was computed and analyzed comparing the selected scenario to the reference scenario (conventional potato yields) for both 2012 and 2020 (see diagram in figure 14).

The evaluation shows that over the medium term (2012), the current regulatory framework will lead to results that lie between those from scenarios 1 and 2: as shown in figure 14, potato yield in the EU-27 could be reduced on average by 20%, decreasing from 29.3 t/ha. to 23.5 t/ha. With regard to the long-term outcomes of the new regula-

tion modifying Directive 91/414/EEC (2020), a forecast with results between those of scenarios 2 and 3 is considered probable: domestic potato yield will be seriously affected under the new regulation, with a possible 33% reduction in output, dropping from 32.7 t/ha. to 21.8 t/ha.

In conducting a more detailed analysis, taking into consideration future agricultural and economic trends, the evaluation shows that over the medium term (2012) potato production in the EU-27 could decrease by nearly 32%, further reducing the self-sufficiency level (in this case to around 80%) and thus leading Member States to import larger quantities of potatoes from extra-EU-27 countries (China, Russian Federation, USA, etc.). With regard to the long-term outcomes, domestic potato production could be seriously affected by a possible 50% reduction and an even worse trade balance, reaching an average deficit of 20 million tons as compared to the 312 thousand ton trade surplus in 2006 (in that year imports accounted for 41% of total domestic use). This would also mean that the EU-27 supply of potatoes would be able to cover just 61% of internal consumption. For both the medium- and long-term scenarios, it is important to point out the significant differences between the "static" and "dynamic" analyses: the large supply gap is mainly due to the striking decrease in the area cultivated with potatoes (especially in Poland) that will occur over the next several years (although at a lower rate).

FIGURE 14 | **DIRECT AND DYNAMIC IMPACT OF THE TWO REGULATORY FRAMEWORKS OVER THE MEDIUM TO LONG TERM (2012–2020)**



WHEAT

DYNAMIC IMPACT	PRODUCTION (MIL. T)	SELF SUFFIENCY
Present situation (2006)	64	105%
Dir. 91/414 (2012)	44	80%
Impact 2006–2012	–32%	–25%
New Regulation (2020)	32	61%
Impact 2006–2020	–50%	–44%

Source: Nomisma – Areté elaborations on Eurostat data.

POTATO PESTS AND THEIR EFFECT ON QUALITY

The effect of pests is also on potato quality and marketability. For example, with regard to tuber size, often the harvested crop cannot be placed on the market because it doesn't reach the minimum standard size of 35 mm. A practical example of this problem in 2007 comes from organic farming in Germany, where the organic potato yield is low and a large share of the crop is below the minimum standard size (thus very difficult to sell). The box 6 shows how quality could be compromised if potato crops are hit by different pests.

BOX 6 | **MAIN POTATO DISEASES AND PEST EFFECTS ON QUALITY**

Pathogens	Late blight (a disease caused by a fungus) can cause significant crop loss in the field and a breakdown of tubers in storage. Potatoes infected with late blight appear shrunken on the outside, corky and rotten inside and are not suitable for consumption. During the first few weeks of storage, temperatures and humidity tend to be high, which offers an ideal environment for the development of late blight that subsequently exposes infected tubers to further invasion by soft rot organisms. Depending on the severity of the disease, complete breakdown of the potato pile can occur. A PPP spray program against late blight could be applied to reduce the potential for tuber infection during harvest. If the late blight fungus is present on green tops at harvest, it may be transferred to tubers during harvest, as tubers and tops make contact during harvest. Other secondary consequences of a pathogen attack are: physiological defects of the tubers, tuber size reduction, rotten tubers increase susceptibility to virus and presence of mycotoxins.
Weeds	Weeds generate competition (particularly for water and nutrients) with the crop. Plants show symptoms of yellowing with low quantity of stems and a reduced tuber production. Furthermore, weeds can serve as hosts for insects that can transmit diseases and increase the need to use insecticides. Also in this case tuber size reduction and yield reduction could occur (small tubers that will not be marketable).
Animal pests	Sucking insects affect the vascular system that reduce photosynthesis, decrease productivity, stunt the plant, and sometimes kill the young seedlings. In the feeding process, leafhoppers inject a salivary toxin that causes injury to the plant. Another effect is the transmission of plant-infecting viruses, resulting on unmarketable potatoes. Early season infection stunts plants, and infections in seed potatoes result in unmarketable crops. Some potatoes also develop a brown discolouring inside which reduces quality. Other chewing insects may devour so much of the vines that the plants die, and the development of tubers is prevented or the yield greatly reduced.
Others	Plant chlorosis, yield reduction, low quality of tuber, suberization problems and skin cracks.

Source: Nomisma elaborations on information from industry experts.

WINE GRAPE

WINE GRAPE PRODUCTION

Over the past several years, the European wine market has developed considerably. In 2006, the EU-27 was the world leader in grape production, representing nearly 40% of the world output. Traditionally, wine grape production has been one of the main widespread permanent crops in Europe. Wine production in the EU-27 in 2006 reached more than 160 million hectolitres. European viticulture is carried on by 1.6 million farms cultivating an area of 3.5 million ha (despite a slight reduction, grapes still account for 28.5% of the total permanent crop area). The three main important countries in Europe in terms of both grape area and wine production are Spain (1.2 million ha and 41 million hl), France (864 thousand ha and 46.3 million hl) and Italy (827 thousand ha and 44 million hl).

With regards to world grape production, in 2006 China was the second largest global producer with 9.2% of the total output, followed by USA and Turkey. However, in order to gain a more detailed picture of the wine grape sector, it is necessary to look at wine production, in which the EU-27 share is 60%, while USA ranks second (8%), followed by Argentina, Australia and China.

Wine-making and wine quality can contribute to a country's image worldwide, with positive effects on consumption of typical foods and non-food products. Good examples of these syner-

gies are seen in France and Italy, which rely heavily on the positive mood and reputation generated by high quality wine production. Effective and successful marketing strategies have allowed European wine producers to gain commercial advantages and increase exports to developed countries and even to emerging markets like China and India. Europe is the main global wine trader, accounting for more than 70% of world wine exports. Again Italy, France and Spain play major roles in this context (these three countries generate almost 60% of EU-27 wine trade). Moreover, since the late 1990s, Europe has also been an active importer of wine from extra-EU-27 countries (i.e. US, Australia, Chile, etc.). In fact, the EU-27 average annual import rate since 1996 is close to 10%, and in 2005 total imports of wine reached 13.2 million hl.

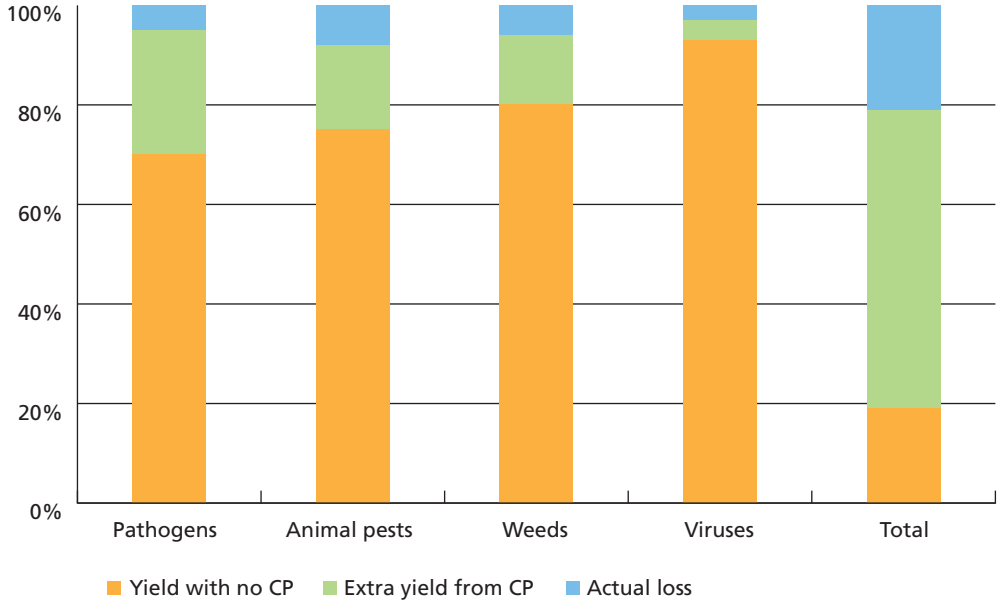
The main objective of the recent EU wine market reform has been to increase quality through area reduction and a focus on better growing and cellar techniques in order to compete more effectively against other global producers and reduce stocks in the internal market. Consequently, a balance between volume (yield) and final quality should be the final target both for producers and consumers.

TABLE 11 | **EU-27 GRAPE AREA AND PRODUCTION (2006)**

	Total area		Total production	
	Mil. ha	Var. 00–06	Bil. €	Var. 00–06
Grapes	3.5	–5.9%	n.a.	
Fruit	12.2	–4.0%	n.a.	
Crops (total UAA)	181.6	–18.8%	142.2	–3.4%
Share of grapes in total permanent crops	28.5%			
Share of grapes in total crops	1.9%			

Source: Nomisma elaborations on Eurostat data.

FIGURE 15 | **IMPORTANCE OF CROP PROTECTION IN GRAPES (% YIELD COMPOSITION)**



Source: Nomisma elaborations on results from agrochemical experts.

GRAPES PESTS' IMPACT ON YIELDS AND THE ROLE OF ORGANIC FARMING

Existing studies and analyses of historical data, comparing various growing conditions, clearly show the effect of crop protection on grape production. The variability of the yield level is a practical demonstration of the significant impact of pests on final output and farmer income. Without crop protection, the attainable wine grape yield is reduced dramatically mainly due to fungal and insect pest damages, and the effects on vineyards could be disruptive, affecting not only the yield and quality of the annual harvest, but also the survival of the plant (figure 15).

Since there is a high variability in wine grape yields across Europe, the estimation of the reduction of yields associated with organic farming for this crop was particularly difficult. On average, organic farming crop yields were estimated as being about 20% lower than yields of crops using conventional methods[8] (box 7).

BOX 7 I **YIELDS OF ORGANIC WINE GRAPES COMPARED TO CONVENTIONAL WINE GRAPES**

COUNTRY	YIELDS OF ORGANIC WHEAT COMPARED TO CONVENTIONAL WHEAT	SOURCE
Spain	80%	Mader et al. (2002); Malusà et al. (2004)
France	80%	Mader et al. (2002); Malusà et al. (2004)
Italy	80%	Mader et al. (2002); Malusà et al. (2004)
Hungary	80%	Mader et al. (2002); Malusà et al. (2004)

Source: Nomisma – Areté elaborations.

There is a large difference in the crop yields achieved using no crop protection whatsoever and what is termed "organic viticulture". This is explained by the fact that organic viticulture makes significant use of some plant protection products that are highly effective against the most common pathologies (especially copper and some insecticides). Since organic viticulture uses some PPPs that are also subject to evaluation in the context of Dir. 91/414/EEC and the proposed new regulation, the evaluation has applied a conservative approach to the estimation of yield reduction.

WINE GRAPE SCENARIO ANALYSIS

By using as a reference the yields of conventional wine grape cultivation (reference scenario) and organic wine grape yields (radical scenario), data show that if wine grape production techniques and the regulatory framework are not subjected to any significant changes, a decline in wine grape yields leads to a reduction in production (table 12). For scenario 1 the reduction in output is estimated as being –8% in 2012 and –4% in 2020, while data regarding scenario 2 and scenario 3 show a reduction in output (on 2006) of 14%–21% in 2012 and of 10%–17% in 2020 (table 12). Similarly, the level of self sufficiency (102% in 2006) would decrease both over the medium and the long term, with a related increase in imported products. According to our evaluation, the EU would have a negative trade balance of 12–14 million hectolitres under scenario 1, 24–26 million hectolitres for scenario 2 and 37–38 million hectolitres for scenario 3.

8 The coefficient of reduction was calculated by taking into account the average data on the yields of organic farming from the study of Mader et al. (2002). In addition, the study of Maulsà et al. (2004) demonstrates that also in the specific case of the wine grape, the average yield in response to organic treatments was about 20% lower than under conventional management.

TABLE 12 | **WINE GRAPE: SCENARIO ANALYSIS (2012-2020)**

	2006	2012				2020			
INDICATOR	**Present situation**	**Scenario 0 (reference scenario)**	**1**	**2**	**3 (radical scenario)**	**Scenario 0 (reference scenario)**	**1**	**2**	**3 (radical scenario)**
Yield (t/ha)	7.1	7.3	6.8	6.3	5.9	7.7	7.2	6.7	6.2
Area (000 ha)	3,548	3'411	3,411	3,411	3,411	3,380	3,380	3,380	3,380
Production (000 t)	25,263	24,950	23,286	21,623	19,960	26,100	24,360	22,620	20,880
Wine production (000 hlt)	179,371	177,146	165,336	153,527	141,717	185,314	172,960	160,606	148,251
Wine domestic use (000 hlt)	175,178	179,696	179,696	179,696	179,696	185,234	185,234	185,234	185,234
Wine export (000 hlt)	15,616	23,609	23,609	23,609	23,609	30,244	30,244	30,244	30,244
Wine import (000 hlt)	12,217	26,159	37,969	49,778	61,588	30,163	42,518	54,872	67,226
Trade Balance (000 hlt)	3,400	–2,550	–14,360	–26,169	–37,979	81	–12,274	–24,628	–36,982
Degree of self sufficiency	102%	99%	92%	85%	79%	100%	93%	87%	80%
Variation on 2006 production		–1%	–8%	–14%	–21%	3%	–4%	–10%	–17%

Source: Nomisma – Areté elaborations on Eurostat data.

THE IMPACT OF THE NEW REGULATION ON WINE GRAPES

For wine grapes, figure 16 summarizes the main estimated impacts of the new regulation on commonly used PPPs, according to the focus group experts.

As was done in the analysis for wheat and potatoes, also for wine grapes the change in the yield (and production) level was computed and analyzed by comparing the selected scenario with the reference scenario (conventional potato yields) for both 2012 and 2020 (see diagram in figure 17). The evaluation shows that over the medium term (2012), the effects of the current regulatory framework will lead to an impact ranging between those of scenarios 2 and 3: as shown in figure 17 wine grape yield in the EU-27 could decrease by an average of 17%, declining from 7.3 t/ha. to 6.1 t/ha. As for the long-term outcomes of the new regulation modifying Directive 91/414/EEC (2020), a forecast result that lies between those from scenarios 1 and 2 is considered probable: also under this regulatory framework will domestic wine grape yield be affected seriously, with a possible 10% reduction, dropping from 7.7 t/ha. to 6.9 t/ha.

When conducting a more detailed evaluation by taking into consideration future agricultural and economic trends, the analysis shows that over the medium term (2012) wine grape production in the EU-27 could decrease by nearly 18%, directly affecting domestic wine production. Such a situation would further reduce the wine self-sufficiency level (in this case to around 82%), thus leading Member States to import larger quantities of this product from extra-EU-27 countries (especially USA, Argentina, Australia, and Chile). Over the long term (2020), domestic grape and wine production is expected to decline slightly, with a possible average reduction of nearly 7% and only relatively minor effects on the trade balance and on the self-sufficiency level (in this case remaining around 90%). In fact, despite the decline in the production level, the import increase is somewhat compensated for by export growth. In sum, it can be observed that, even though the detailed evaluation takes into account several variables (area, consumption, trade balance, etc.), the final results are not significantly different from those estimated in the first assessment. In particular, through 2020 various dynamics tend to weaken the negative effects of the new regulation (–10% to –7%).

GRAPE PESTS AND THEIR EFFECT ON QUALITY

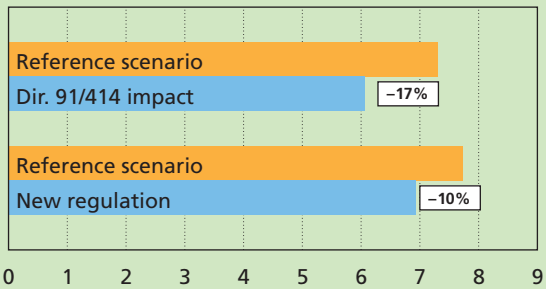
Wine consumption has decreased in volume in traditional producing countries (France, Italy, Spain), but other markets have discovered this product quite recently, thanks to a higher and more homogeneous quality level. In fact, quality improvement has been the key factor driving wine production in the past 20–25 years. Quality assessment is not so easy to define, and often sugar content is regarded as a differential element in commercial consideration (while consumers choose wines according to a broader concept of taste). However, the quality level is highly dependent on grape characteristics, which in turn are strongly affected by pests. Insects, for example, represent an important cause of yield and quality losses in grapes. Damage from these pests could have direct and indirect effects (increasing the risk of fungal or bacterial contamination). On the other hand, bacterial diseases have a direct effect on wine quality and safety, interacting with fermentation and affecting wine taste. Box 8 shows how quality could be compromised when grape crops are hit by different pests.

FIGURE 16 | **WINE GRAPE: IMPACT OF PPP REGULATION CHANGE**

PRODUCT LINE	ESTIMATED IMPACT ON WINE GRAPE
Herbicides	Current weed control uses nonselective and residual herbicides in some countries (or mix between them). Looking at the new regulation replacing 91/414 both two groups will be resized dramatically. The only two alternatives will be mechanical control (increasing risks of soil erosion) or mulching
Fungicides	Important contact fungicides like some acetamides, dithiocarbamates, morpholines and others, will be significantly reduced with a dual effect: more difficult control of powdery and downy mildew and resistance issues increase
Insecticides	The overall reduction of organophosphates and pyrethroids will affect insect control in grapes either through direct insect suppression and prevention of other diseases carried out by insects
Impacts between scenario 2 and 3 results in 2012 and between 1 and 2 results in 2020	

Source: Nomisma elaborations on results from agrochemical experts focus group.

FIGURE 17 | **DIRECT AND DYNAMIC IMPACT OF THE TWO REGULATORY FRAMEWORKS OVER THE MEDIUM TO LONG TERM (2012–2020)**



WINE DYNAMIC IMPACT	PRODUCTION (MIL. T)	SELF SUFFIENCY
Present situation (2006)	179	102%
Dir. 91/414 (2012)	148	82%
Impact 2006–2012	–18%	–20%
New Regulation (2020)	166	90%
Impact 2006–2020	–7%	–12%

Source: Nomisma – Areté elaborations on Eurostat data.

BOX 8 | **MAIN WHEAT DISEASES AND PEST EFFECTS ON QUALITY**

Pathogens	Infection of grape berries by powdery mildew (a fungus disease), a pathogen which degrades the quality of the fruit, juice and wine prepared from these fruits, starting from as low as a 10% diseased rate. If not controlled, powdery mildew reduces vine growth, yield, and winter hardiness. In addition, this disease gives an undesired, off-flavour to wine, but it is not a concern for grape juice. If a downy mildew (another fungus disease) infection occurs during blossoms and grape clusters, it can result in up to 100% yield loss and later disease attacks reduce quality. Botrytis bunch rot can destroy entire bunches, resulting in 25–50% yield losses in susceptible varieties and having a high impact on quality due to destruction of anthocyanins and fruit flavours.
Weeds	Weeds generate competition for water and nutrients. They also represent hosts for pests and diseases. Depending on the species, the direct effects on the vines varies.
Animal pests	Young vines may be killed if girdled and older vines may decline over a period of years. A kind of larva attacks the grape directly and promotes the growth of diseases such as Botrytis and Aspergillus that produce mycotoxins. Leafhoppers transmit phytoplasm, while trips decrease quality of table grapes.

Source: Nomisma elaborations on information from industry experts.

CEREALS

CEREAL SCENARIO ANALYSIS

On the basis of the results obtained from the analysis for each crop under study, it is possible to develop some considerations that help in identifying the general impact of the changes in PPP regulation on the European agricultural system.

TABLE 13 | **CEREALS: SCENARIO ANALYSIS (2012–2020)**

	2006	2012				2020			
Indicator	**Present situation**	**Scenario 0 (reference scenario)**	**1**	**2**	**3 (radical scenario)**	**Scenario 0 (reference scenario)**	**1**	**2**	**3 (radical scenario)**
Yield (t/ha)	4.9	5.0	4.5	4.0	3.5	5.4	4.8	4.3	3.7
Area (000 ha)	59,296	57,533	57,533	57,533	57,533	56,935	56,935	56,935	56,935
Production (000 t)	292,898	290,081	260,882	231,683	202,484	304,774	274,098	234,422	212,746
Value (min €)	42,779	42,369	38,110	33,852	29,594	44,515	40,041	35,567	31,094
Domestic use (000 t)	246,026	267,994	267,994	267,994	267,994	287,367	287,367	287,367	287,367
Export (000 t)	15,382	12,517	12,517	12,517	12,517	11,613	11,613	11,613	11,613
Import (000 t)	12,260	–9,569	19,630	48,829	78,028	–5,793	24,883	55,559	86,235
Trade Balance (000 t)	3,122	22,087	–7,113	–36,312	–65,511	17,407	–13,269	–43,945	–74,621
Degree of self sufficiency	119%	108%	97%	86%	76%	106%	95%	85%	74%
Variation on 2006 production		–1%	–11%	–21%	–31%	–4%	–6%	–17%	–27%

Source: Nomisma – Areté elaborations on Eurostat data.

With regard to the cereal sector (table 13), the evaluation was based on the same methodology used for the case study crops and it provided a satisfactory overview of the overall impact on the European cereal branch, by showing the foreseeable change in yields resulting from changes in the PPP regulation.

FIGURE 18 | **MAIZE: IMPACT OF PPPS REGULATION EVOLUTION**

PRODUCT LINE	ESTIMATED IMPACT ON MAIZE
Herbicides	Pre emergence key ASs like triazines, chloroacetalinilides, dinitroanilines and others will experience strong limitation in use. Post emergence herbicides will not completely control weed competition. This aspect could reinforce arguments in favour of HTC corn introduction (GMO). Perhaps the introduction of new ASs after 2012–15 could moderate that effect.
Fungicides	Not significant
Insecticides	New regulation replacing 91/414 will significantly affect Pyrethroids and Organophosphates, crucial for Ostrinia control. The main effect will be on feed quality and increase of aflatoxins.
Impacts between scenario 2 and 3 results in 2012 and between 1 and 2 results in 2020	

Source: Nomisma elaborations on results from agrochemical experts focus group.

In particular, data show that the reduction of output will range from –11% (scenario 1) to –31% (scenario 3) over the medium term and from –6% (scenario 1) to 27% (scenario 3) over the long term. It can be assumed that such a reduction will increase the dependence of the EU cereal branch on imported products (which are projected to increase substantially, especially under scenario 2 and scenario 3). Moreover, the decrease in EU cereal production would reduce the level of self-sufficiency, which is estimated as ranging from 74% to 97%, compared to the current level of 119%.

THE IMPACT OF THE NEW REGULATION ON CEREALS

An evaluation of the impact of the regulatory changes on the entire cereals branch was carried out by starting from the case study on wheat and taking into consideration the weight of maize in cereal crops (in figure 18 the experts have highlighted the estimated impacts on the most common PPPs used in maize cultivation that will likely be affected by the changes in the regulation).

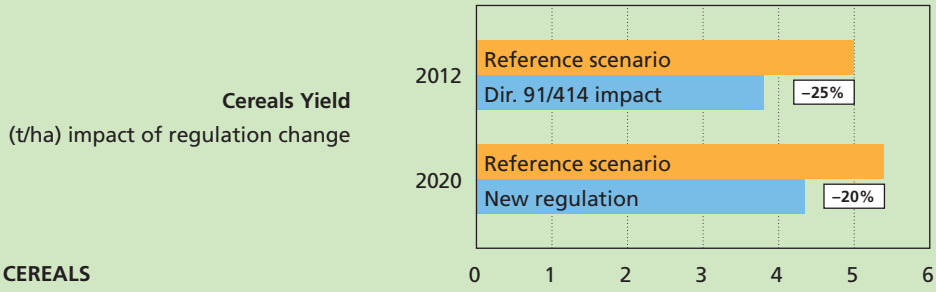
As undertaken for the previous three case studies, first of all the variation in the yield (and production) level was computed and analyzed comparing the selected scenario with the reference scenario (conventional cereal yields) for both 2012 and 2020 (see diagram in figure 19). The evaluation shows that over the medium term (2012), the effects of the current regulatory framework will lead to results that fall between those for scenarios 2 and 3: as shown in figure 19, cereal yields in the EU-27 could decrease an average of 25%, dropping from 5 t/ha. to 3.8 t/ha.

With regard to the long-term outcome under the proposed new regulation, in contrast to the results for wheat, for maize a forecast ranging between the production levels of scenario 1 and 2 is considered probable, thanks to the probable introduction of new ASs after 2012–2015. Thus, with regard to all cereals, scenario 2 could be indicated as the most likely: domestic cereal yield will be significantly affected by the regulation as well, with a possible 20% reduction, dropping from 5.4 t/ha. to 4.3 t/ha.

In conducting a more detailed analysis to determine dynamic impact, taking into consideration future agricultural and economic trends, the evaluation shows that over the medium term (2012) cereal production in the EU-27 could decrease by nearly 26%, further reducing the self-sufficiency level (in this case to around 81%) and thus leading Member States to import larger quantities of cereals from extra-EU-27 countries (especially from Canada, USA, Argentina, Brazil, and India). With regard to the long term outcomes, domestic cereal production will be seriously affected, with a possible 22%

reduction and an even worse trade balance, reaching a 44 million ton deficit compared to the 3 million ton surplus in 2006. Such a deficit is further exacerbated by the expected increase in domestic cereal consumption throughout the period (+17%), while self-sufficiency is around 85%. In sum, it can be observed that, even though the dynamic impact analysis comprised the forecasted changes of various indicators (area, consumption, trade, etc.), the final impact results are pretty much the same as in the first assessment and are quite substantial in the wheat case study.

FIGURE 19 | **DIRECT AND DYNAMIC IMPACT OF THE TWO REGULATORY FRAMEWORKS OVER THE MEDIUM TO LONG TERM (2012–2020)**



CEREALS		
DYNAMIC IMPACT	**PRODUCTION (MIL. T)**	**SELF SUFFIENCY**
Present situation (2006)	293	119%
Dir. 91/414 (2012)	217	81%
Impact 2006–2012	–26%	–38%
New Regulation (2020)	228	85%
Impact 2006–2020	–22%	–34%

Source: Nomisma – Areté elaborations on Eurostat data.

CEREAL TRENDS

It is expected that world agricultural trends will be particularly dynamic over the next few years. Throughout 2006 and 2007, the sharp increases in the prices of the main cereals (+75% wheat, +37% maize) and oil-seed crops (especially soybeans with +59%) have already provided clear signals in this direction.

Various factors have contributed to this price spike, not the last of which has been a series of dry weather spells which have decreased water resources and limited output in some of the most important producing countries (particularly Australia), significantly reducing global supply. While it is true that cyclical elements, like scarce precipitation, hail or spring frosts, are present in most agricultural areas, it is also true that the trend in increasing average temperatures caused by human activity could make destabilizing climatic conditions more frequent. In such a scenario, the management of increasingly limited water resources for irrigation could become a crucial factor in determining the productivity of agricultural systems.

Yet, over the last two years and even more so over the next few years, it has been the demand side that has and will continue to show evidence of structural change. There are two main factors in this development:

- First of all, it is necessary to highlight the growth in demand for food products, especially of animal origin, in the emerging economies (Brazil, Russia, India and China, to mention only the most important ones), with population and spending capacities that are growing in line with the high rates of GDP growth. Following the same trends seen in the past in the industrialized countries, strong economic growth leads to new food consumption patterns, characteristic of the higher economic level achieved: shifting from a diet prevalently comprised of products of vegetal origin, there is an increasing uptake of products of animal origin (meat, dairy products, etc.). This is occurring both through rising imports, as well as primarily a sharp increase in animal production in loco, which will lead to a significant increase in imports of animal feed, with maize and soybeans representing the principal elements.

- Secondly, the global expansion of the bio-fuels industry (in which the United States has registered the highest rates of growth) – aimed at both reducing dependence on petroleum and limiting environmental impact resulting from the production of energy – will lead to a high rate of demand for "energy" crops: maize, sugar cane, soybeans, colza, sunflowers are the most important of these crops. This can also have limiting effects on the production levels of other crops, such as has been happening in the United States, where the high demand for maize has led to a reduction of the area cultivated with wheat (with the maize area exceeding the wheat area for the first time since the 1940s) and with soybeans.

The world supply of agricultural products thus has to make a significant effort to satisfy the pressure of demand, which according to the main institutes involved in global forecasting, will continue to grow over the next decade at a rate of 8% for wheat and 35% for maize. And it is particularly for the latter case, that animal feed and bio-energies will have an extraordinary impact in determining growth (table 14).

Such dynamics, coupled with the trend toward liberalization of trade flows affected by WTO agreements, will lead to accelerated levels in the volume of world trade: in particular, such increases are estimated to reach 17% for wheat and 26% for maize.

TABLE 14 I **WORLD FORECASTS 2016 FOR WHEAT AND MAIZE**

FORECASTED VARIATION 2016/2006 (%)	WHEAT	CORN
World demand (tons)	8%	35%
of wich: Feed use	2%	9%
Food and other uses	9%	42%
World trade (tons)	17%	26%

Source: Nomisma – Areté elaborations on Fapri data

The agricultural sectors of many countries could benefit from such a scenario, beginning with the large emerging economies, Brazil and Argentina, which are becoming increasingly important as world suppliers of many commodities, and the two Asian giants, which, however, tend to produce more for their own enormous demand than for export. Their main competitive advantages are based on low cost labor, significant reserves of unutilized terrain, high levels of medium-sized companies, and, in general, enormous margins for increases in agricultural yield, which little by little is being introduced by more extensive use of mechanized and technical means.

At first glance, in contrast to the emerging economies, the situation in the industrialized north shows far less margin for growth on the one hand, due to a level that already extensively uses mechanical and technical means, and, on the other hand is less competitive mainly in terms of costs. In any case (especially in USA and Australia) the high average dimensions of farms are able to overcome these disadvantages to some extent, which however does not hold true in the case of the EU: the smaller dimensions of farm enterprises and problems related to generational change in agricultural professions has made the probability that Community agriculture will maintain its competitiveness even more uncertain, especially if considered within the context of decreasing CAP support.

5 CONCLUSIONS

The revision of Directive 91/414/EEC is expected to change substantially the main legal instruments that govern crop protection products in Europe. As a result of this revision process, it can be foreseen that a considerable number of PPPs, which are currently on the market, will be no longer authorised in the future. At the same time, a significant amount of time and effort will be required for the crop protection industry to research, develop and bring to the market new substances which will be compliant with the new regulatory framework.

Within this perspective, it becomes clear that an overall assessment of the impacts on crop yields of the changes in the PPP regulatory framework will be possible, on the one hand, only at the end of the process of revision of existing active substances on the market and, on the other hand, after a more focused evaluation of the time and the resources needed in developing new PPPs. Despite these important constraints, the present study has sought to identify to what extent the likely changes in the current PPP regulatory framework could affect crop yields by estimating a range of yields, taking into account different "levels of change" from the present PPP regulation.

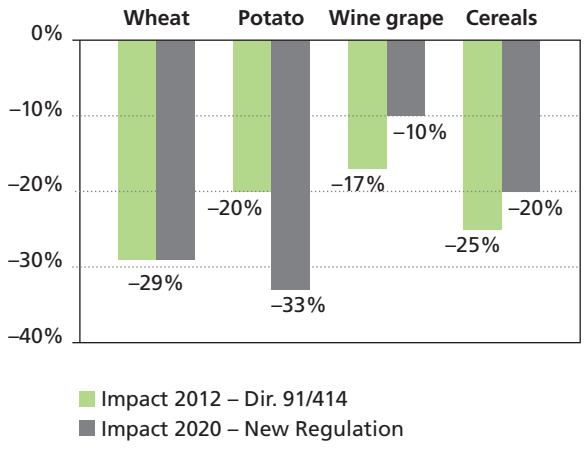
In order to estimate the possible effects that the changes in the PPP regulatory framework could have on the EU-27 agricultural production system, hence on the Agri-food sector, a quantitative analysis was undertaken. It was decided to analyze several case studies (three different crops) and to create different scenarios for each of them in order to provide relevant results that could be qualitatively generalized for agriculture as a whole. The three crops selected were wheat, the potato and the wine grape, which are products representative of central and northern Europe and the Mediterranean area, respectively. In addition, an evaluation of the cereals branch was also undertaken.

Depending on the scenario, the analysis has generated different sets of results (defined by the values of various indicators selected) for the medium (through 2012, effects of Dir. 91/414/EEC) and long-term (for 2020, effects of the new regulation) timeframes.

Figure 20 clearly shows the direct impacts of the current legislation (2012) and the proposed Regulation (2020) on the different crop yields (hence on their overall production).

It should be noted that by 2012, Dir. 91/414/EEC will likely have varying effects on different crops. In particular, wheat yields and production will decrease by 29%, which represents a higher impact than experienced by the cereal branch as a whole (–25%). The new regulation could cause the same level of reduction in yield and production in 2020. With regard to the potato, it was estimated that Dir. 91/414 will have quite a significant impact on 2012 production (–20%), but even a sharper decline (–33%) will likely occur by 2020 due to the implementation of the new rules. Finally, the impact assessed for wine grapes over the medium term (2012) was a drop in output of –17%, while by 2020 the PPP supply will probably be able to adapt to the new normative framework, and resulted in a far lower loss of productivity (–10%). Given that organic viticulture uses some PPPs that are also subject to evaluation in the context of Dir. 91/414/EEC and the proposed new regulation, the evaluation has applied a

FIGURE 20 | **DIR. 91/414/EEC AND NEW REGULATION: YIELD IMPACTS ON MAIN CROPS IN MEDIUM AND LONG TERM PERSPECTIVES**



Source: Nomisma – Areté elaborations on Eurostat data.

conservative approach to the estimation of yield reduction. In sum, cereals (mainly wheat and maize), as well as wine grapes, will experience greater negative impacts from the full application of the current regulation in 2012 than from the new proposed directive in 2020. In fact, cereals were estimated to experience a 25% decline in 2012 compared to a 20% drop in 2020.

Generally speaking, while there remain substantial differences between the yield and production losses of the various crops (due to reduced PPP availability), it can be stated that the decreases are all quite significant – even if the new proposed regulation in some cases generates lower negative impacts than the current one.

In any case, the above assessment only provides estimates of one of the impacts resulting from the two different regulatory frameworks, without taking into consideration any future agricultural and economic trends. Thus, to provide a more detailed understanding of the various dynamics that might affect the development of European agriculture in the future, several other important indicators were introduced. For each crop, potential development trends within the two forecasted periods, 2006–2012 and 2006–2020, have been identified (dynamics related to yields, cultivated surface areas, production, domestic consumption and the trade balance). Incorporating these variables into the four different scenarios has permitted observing the likely effects of the PPP regulatory framework coupled with the future estimated trends for the above indicators. Thus, each detailed analysis related to the target crops comprises both an element related to the effects on the availability of PPPs as well as the overall agricultural and economic trends.

The main findings of this research can be summarized as the following:

Wheat: over the medium term (2012 – prevalent Dir. 91/414/EEC effects), wheat production in the EU-27 could decrease by nearly 30%, further reducing the level of self-sufficiency (71%) and thus leading Member States to import larger quantities of wheat from extra-EU-27 countries (especially Canada, Australia, the Russian Federation, Ukraine and USA). As to the long-term impacts of the new regulation (2020), domestic wheat output will be seriously affected as well, with a possible 27% reduction and an even worse trade balance. Such a trade deficit would be even further exacerbated by the expected increase in domestic wheat consumption over the period, while self-sufficiency remains around 70%.

Potatoes: over the medium term (2012), potato production in the EU-27 could decline by nearly 32%, further reducing the level of self-sufficiency (80%) and thus leading Member States to import larger quantities of potatoes from extra-EU-27 countries (China, Russian federation, USA etc.). With regard to the long-term impacts of the new regulation (2020), domestic potato output could be dramatically affected by a possible 50% drop in production and a seriously exacerbated trade balance. For both the medium- and long-term scenarios, it is important to point out the significant differences between the "static" and "dynamic" analyses: the large supply gap is mainly due to the striking decrease in the area cultivated with potatoes (especially in Poland) that will occur over the next several years (although at a lower rate).

Wine: over the medium term (2012), grape production in the EU-27 will decrease by nearly 18%, directly affecting domestic wine production. Such a situation will further reduce the wine self-sufficiency level (82%), thus leading member states to import larger quantities of this product from outside the EU-27 (especially USA, Argentina, Australia, and Chile). As to the long-term outcomes of the new regulation (2020), domestic grape and wine output would decrease around 7% with correlated effects on the trade balance and self-sufficiency level (90%). While there is decline in the production level, the increase in imports would be somewhat balanced by export growth.

Cereals: over the medium term (2012), cereal production in the EU-27 could drop by nearly 26%, further reducing the level of self-sufficiency (81%), and leading member states to import larger quantities of cereals from extra-EU-27 countries (especially from Canada, USA, Argentina, Brazil, India). As to the long term outcomes of the new regulation, domestic cereal production will be seriously affected, with a possible 22% reduction in output and a worse trade balance. Such a trade deficit is further exacerbated by the expected increase in domestic cereal consumption throughout the period, while self-sufficiency will be around 85%.

TABLE 15 | **NEW PROPOSED PPP REGULATION: IMPACTS ON THE MAIN EU AGRICULTURAL CROPS OVER THE MEDIUM TO LONG TERM (2012–2020)**

	IMPACT 2006–2012			IMPACT 2006–2020		
	Present situation (2006)	Dir 91/414/EEC Impact (2012)		Present situation (2006)	New regulation Impact (2020)	
WHEAT						
Production (Mil. t)	135	94	–30%	135	99	–27%
Self sufficiency	104%	71%	–33%	104%	70%	–34%
POTATO						
Production (Mil. t)	64	44	–32%	64	32	–50%
Self sufficiency	105%	80%	–25%	105%	61%	–44%
WINE						
Production (Mil. hlt)	179	148	–18%	179	166	–7%
Self sufficiency	102%	82%	–20%	102%	90%	–12%
CEREALS						
Production (Mil. t)	293	217	–26%	293	228	–22%
Self sufficiency	119%	81%	–38%	119%	85%	–34%

Source: Nomisma – Areté elaborations on Eurostat.

The analysis has demonstrated that the current and the proposed regulations on PPP market access can have potential negative effects on present agricultural trends and could lead to a weakening of Europe's position in world agricultural and Agri-food markets. Indeed, while for wheat and wine grapes the production losses under the two different scenarios are relatively consistent, for potatoes, which are currently undergoing a significant restructuring process, the effects of the new regulation could lead to an even further deterioration of EU-27 productivity.

The crops covered in the present analysis represent a significant share of the total EU-27 utilised agricultural area (UAA). Therefore, considering the results of this study, it may be argued that the entire EU agricultural sector could be similarly affected by the changes in the PPP regulatory framework. In other words, the changes in terms of production and self-sufficiency levels estimated for these groups of crops may be considered also to be relevant for other crops not covered in the present analysis.

In addition, the reduced availability of PPPs can have important effects on the quality of primary resources. As illustrated in the various case studies, the absence of pathologies or competition by weeds generates a direct impact on the characteristics of agricultural products and thus on their commercial value.

Finally, we provide some final considerations related to the main conclusions of the first part of the study.

1. The study results demonstrate a foreseeable reduction of agricultural self-sufficiency of the EU-27 that will have to be compensated to some extent by a further increase in imports. In a global scenario, international markets are currently particularly sensitive to heightened demand and a consequent escalation of prices.
2. A decline in European production could compromise the competitiveness of the Agri-food sector. This situation could lead to a dual loss. First of all, the EU-27 would not be able to take advantage of new market segments that are currently developing in emerging economies (China, India, etc.), which demand agricultural and food products in increasing quantities, thanks to accelerated population and income growth. Secondly, the EU-27 could even lose part of its current export share, resulting in significant impacts on the entire economic system.
3. The loss of competitiveness could be even more dramatic for the high quality products (for example, Protected Designation of Origin – PDO, Protected Geographical Indication – PGI), which represent important elements of European culture and lifestyle and one of the most important competitive advantages of the EU-27 in international markets.
4. Food safety is an important requirement for European citizens. A decline in agricultural productivity could compromise the current system of quality and safety guarantees in the sense that Europe would become more dependent on supplies of primary resources from extra-EU sources, which are not able to offer the same sanitary and health guarantees.
5. A decline in the capacity for self-sufficiency in primary agricultural products will create inevitable negative repercussions throughout the Agri-food sector and in related sectors of the economic system (wholesale and retail trade, services to companies, financial activities and transport, etc.).
6. Ensuring the competitiveness of European agriculture thus also means supporting the other functions (preservation and protection of the environment, the territory and the landscape as well as animal welfare, the development of integrated economic activities, etc.) it plays and providing them with a future.

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Eurostat:http://epp.eurostat.ec.europa.eu
Faostat: http://faostat.fao.org
WTO international trade statistics: http://www.wto.org

NOTES

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