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NOTE

Policy Department B
Structural and Cohesion Policies

The Consequences of the "cut off" Criteria for Pesticides: Agronomic and Financial Aspects

AGRICULTURE

2008

EN

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Directorate General Internal Policies of the Union

Policy Department Structural and Cohesion Policies

AGRICULTURE AND RURAL DEVELOPMENT

The Consequences of the 'cut off' Criteria for Pesticides: Agronomic and Financial Aspects

NOTE

Content:
The current Commission proposal concerning "The placing on the market of plant protection products", updating Directive 91/414, and the E. Parliament first reading decision contain the 'cut-off' or exclusion criteria which, if adopted would have a devastating effect on farmers' ability to grow a significant number of products. They do not recognise the critical importance of pesticides in controlling and eliminating crop diseases and pests and in increasing crop yields across the EU.

The aim of the note is to assess the scale and magnitude of the potential losses for the EU farmers, in the case that the new regulation is adopted.

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Executive summary

The introduction of hazard based approval criteria in the Regulation amending Directive 91/414/EEC[1] concerning the placing on the market of plant protection products (PPP) is apparently necessitated as a result of the augmenting and influential concerns of some groups of European citizens Risk assessment and management through mitigation measures is the cornerstone of Dir. 91/414 and has been the scientific base for the withdrawal of almost 75% of active ingredients existing in Europe before 1993.

Many risk based decisions for approval of active ingredients, taken so far in the context of Dir. 91/414, although they are proven to be safe according to current scientific knowledge, they will have to be withdrawn under the new hazard based criteria.

The proposed Regulation also comprises of certain policies regarding:

a) the enhancement of the use of mutual recognition through the setting of zones where agronomic conditions are considered to be identical. For indoor uses the entire EU is considered as one zone and for outdoor uses three zones are set.
b) The grading of approved substances with respect to their risk potential, either as candidates for substitution or as low risk and basic substances.
c) The European Parliament first reading decision also proposed a pesticide passport for every raw agricultural commodity that is to be sold. It is also notable that a complement to the Regulation amending Directive 91/414/EEC concerning the placing on the market of plant protection products is also proposed, in the form of the Directive for the sustainable use of pesticides.

Regarding 'cut-off' criteria, Council Common Position is mostly echoing the Commission original Proposal. It also assimilates much from the European Parliament first reading Decision. The main resulting differences can be summarized as the non inclusion by the Council of:

a) a wording about the embryonic, childhood and combination effects concerning Endocrine Disrupting properties,
b) immunotoxic and developmental neurotoxic properties as 'cut-off' criteria,
c) CM3 classification fulfilling the Toxicity criterion for PBT
d) a hazard quotidian for bee toxicity as 'cut-off' criterion.

Also the European Parliament first reading Decision proposes for candidates for substitution to be approved only once and for less years than conventional a.i.

An impact analysis is expected to provide a reliable account of real impacts both positive and negative. Unfortunately no such comprehensive attempt has been made so far regarding the proposed amendment of Dir. 91/414. The Commission's impact assessment came too early in the process and mainly reflected the outcome of possible scenarios for policies that needed to be addressed. Ambiguity generated from the lack of agreed scientific principles for the definition of some of the 'cut-off' criteria, namely the endocrine disrupting potential of a substance and some environmental criteria, lead to different interpretations and results about the number of affected a.i.

[1] OJ L230,19.8.1991.

KEMI of Sweden, using 'formerly applied national criteria and principles' concludes that 23 active ingredients will be withdrawn under the Council Common Position 'cut-off' criteria, whereas PSD of the UK taking into account Commission original Proposal and European Parliament first reading Decision, predicts the loss of either 46 or 118 active ingredients respectively. Because PSD based their assessment mainly on a report sponsored by the Commission, regarding endocrine disruptors, their findings acquire more leverage, and form the basis for a series of reports about agronomic and other speculated impacts.

According to those reports, arable crops like wheat, potato, oilseed rape and sugar beet will face yield reductions and loss of revenue that may well render them unprofitable. The same applies for fresh fruits and vegetables, grapes and ornamentals. Widespread ramifications are depicted as aggravating the already fragile crop protection arsenal left currently at the disposal of the European farmer. Several major crops synonymous with MS, like tulips for the NL, olives for South MS, potatoes for Ireland, wheat for the UK, apples and grapes for central MS etc, will be faced with a lack of, or a small insufficient number of solutions.

Polycyclic diseases with a potential for sexual and asexual reproduction, as well as insects with multi generations in one season will develop resistance as alternations of pesticides with different modes of action will no longer be possible. GM varieties of arable crops also require use of pesticides, either to help them establish in a weed free environment (i.e. glyphosate ready crops) or to protect them from other pests and enemies (i.e. a crop resistant to insects also has to be protected against fungal diseases and weed competition). It is also true that for non arable perennial crops commercialization of genetically modified varieties is neither feasible nor anticipated. For all the above limitations, GM technologies can only provide part of the solution for integrated pest management.

European farmers managed until now to attain world record yields that contributed to the food self sufficiency of the continent. In case the worst scenarios are confirmed, regarding the impact of 'cut-off' criteria, European agricultural economy and related upstream and downstream industries will wither and Europe will become a net importer of agricultural products, while consumers will not have secured access to reasonable 'price, choice and quality of food'. No conclusive report has as yet challenged these arguments.

But the eventuality of depending more upon imports to satisfy European food demand would inevitable expose European consumers to higher risks, as imported fruits, vegetables and cereals exhibit two to three times the exceedances of Maximum Residue Limits than those produced in the EU.

The actual impact of the 'cut-off' criteria will directly correlate with the scope, extent and clarity of the definitions. Rigid and agreed definitions are necessary in order to assess and balance their impact with respect to the twin objectives for reducing the impact while protecting the crops. Only then, can a conscious and informed decision be made for the benefit of all people in the EU. We must also consider that in order to achieve a sustainable and viable agriculture industry in the EU we would have to impose, from farmers and trade partners outside the EU, similar standards to provide European consumers with the safety level envisaged by the proposed legislation for pesticides.

Contents

1. INTRODUCTION

The aim of this briefing note is to provide a comprehensive review of possible impacts from the new provisions proposed in the Regulation[2] amending Directive 91/414/EEC[3] 'concerning the placing on the market of plant protection products'. Among the most controversial issues is the introduction of 'cut off' criteria for the centralized evaluation of active ingredients of plant protection products.

Since 1993 Dir. 91/414 has set risk based criteria for placing on the market of plant protection products. Firstly, under the precautionary principle, producers of active ingredients of plant protection products (Notifiers) are obliged to demonstrate that their product can safely be used for crop protection. A Rapporteur Member State (RMS) is centrally assigned to prepare a Draft Assessment Report (DAR), an evaluation of the required studies provided by the Notifier. The DAR is then Peer Reviewed by EFSA and the Member States. Conclusions from this peer review form the basis of the Draft Review Report (DRR) of the Commission and substantiate its Proposal for the inclusion or not of the active ingredient in the first Annex to the Directive (ANNEX I). This annex is therefore considered to be a list of the active ingredients allowed to be used in the EU. This evaluation is 'source specific', meaning that safety is related to specifications of the technical material of the Notifier, but also sets the standards for generic producers, who have to demonstrate the equivalence of their technical material and prove that they have access to certain protected data.

In a risk based approach thresholds of acceptable exposure are calculated.

Pivotal studies define the:

NOAEL

(no-observed-adverse-effect level) Using **safety factors** (at least 100)

ADI

(acceptable daily intake) for subchronic or chronic exposure

AOEL

(acceptable operator exposure level) for repeated exposure

ARfD (Acute Reference Dose) are calculated

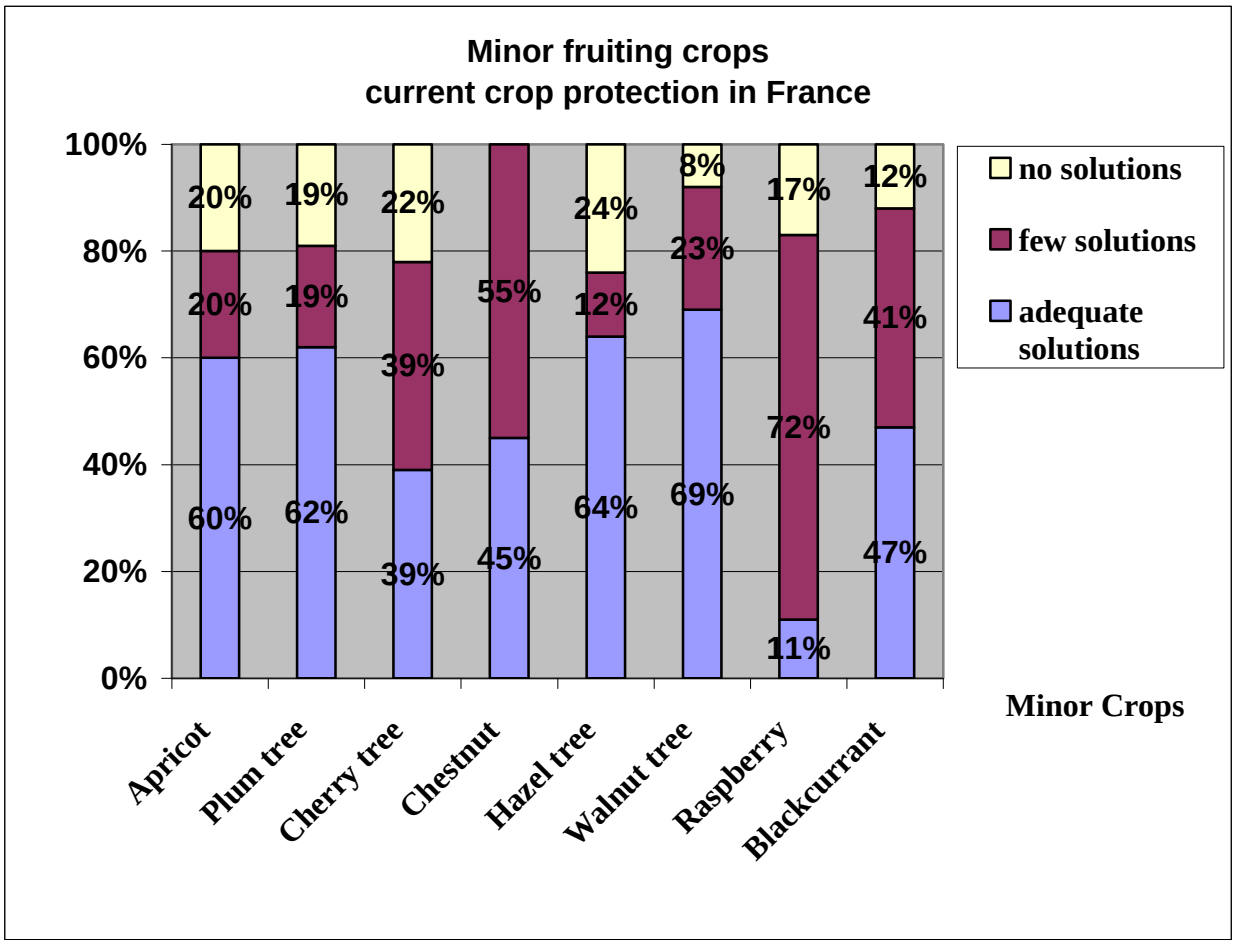
As a second step, following the subsidiarity principle and again under the precautionary principle, anyone wishing to circulate a certain plant protection product within a MS, has to apply to the Competent Authority of that MS, demonstrating that all intended uses are safe. As harmonization is one of the primary goals of all relevant legislation, the possibility for mutual recognition of assessments and/or approvals of plant protection products between MS, is foreseen in Dir. 91/414, but it was applied with limited success and mainly through bilateral agreements.

[2] COM(2006) 388.
[3] OJ L230,19.8.1991.

In both levels, centralized and at MS, evaluations are made in the expert fields of: physicochemical properties, toxicology (classification, exposure and labelling), eco-toxicology, fate and behaviour, Maximum Residue Limits (MRL) and efficacy.

For the re-evaluation of active ingredients already on the market in the EU before 1993, a programme was agreed, comprising of four lists, of almost a thousand active ingredients At the offset, the programme had to generate an extensive grid of common principles and guidelines, administrative and cooperation hurdles had to be overcome, and after the completion of the first list of active ingredients the role of EFSA had to be incorporated. In the 2001 report from the Commission to the European Parliament (EP) and the Council[4] it was evident that progress of decision making was not sufficient, with only 61 decisions taken at that stage, but it gathered momentum afterwards and amounted to 882 decisions (188 inclusions in ANNEX I and 694 withdrawals) around the end of 2008 with decisions on 36 active ingredients pending. During this time 82 new active ingredients were also included in ANNEX I. One of the results of this procedure is the fact that various crop protection problems, especially for minor crops, have no or a small number of chemical solutions.

Graph. 1: FNPF 2008 (joint research by Sous Direction de la Qualité et de la Protection des Végétaux/Services Régionaux de la Protection des Végétaux and Centre technique interprofessionnel des fruits et légumes)



[4] COM(2001) 444.

Regulation (EC) 396/2005[5] on maximum residue levels (MRL) of pesticides in or on food and feed of plant and animal origin, as a complement to Dir. 91/414, advanced the aim of a harmonized common market by setting EU MRL for every agricultural commodity and active ingredient of plant protection products combination.

Elaborating the scope of the plant protection products legislation, the Commission, as required by both the Council and the European Parliament, together with the proposed amendment of Dir. 91/414 brought forward a Framework Directive on the Sustainable Use of Pesticides[6], aiming to further mitigate the risks related with the actual use of plant protection products. This action will extend the safety and risk mitigation attained at the registration phase also to the use phase of plant protection products, primarily by promoting Integrated Pest Management (IPM) and training for the end users and the distribution chain.

Two more pieces of legislation regarding the Statistics[7] and Application Equipments[8] of plant protection products will wrap up the sector package, providing the tools for the accomplishment of the overall objective of reducing 'the impacts of pesticides on human health and the environment, and more generally to achieve a more sustainable use of pesticides with the necessary level of protection against pests'.

[5] OJ L70, 16.3.2005.
[6] COM(2006) 373.
[7] COM(2006) 778.
[8] COM(2008) 535.

2. MAIN AMENDMENTS FOR DIR. 91/414 (still under debate)

2.1 Mutual recognition and Zones

In order to enhance the use of mutual recognition, for which under Dir. 91/414 agronomic comparability had to be proven, the concept of Zone, where agronomic comparability is taken for granted, is introduced. For indoor uses (greenhouse, post harvest etc) the entire EU is considered to be one zone. For outdoor uses three zones (south-central-north) are defined. By way of derogation a MS is allowed to impose additional conditions or even reject the approval, as long as a technical or scientific justification can be provided with respect to special circumstances regarding the protection of crops, human health or the environment.

Since the re-evaluation programme of existing active ingredients is concluded, commonly accepted review reports can be generated for every plant protection product, it is therefore preferable to avoid duplication of administrative work and shift resources to actual surveillance of the use of plant protection products.

In the European Parliament first reading Decision, a one zone approach is envisaged for all (in and outdoor) uses. Such an approach is not expected to remedy the scrappy implementation of mutual recognition attained so far, and as a consequence its obligatory enforcement will also restrain the balanced development of core expertises across the EU, expertises also required for the successful surveillance of the use of plant protection products within every MS.

The Common Position of the Council[9] comprehensively reiterates the proposal for the separation of the EU in three zones for outdoor uses, and also provides for the possibility of application for mutual recognition by any stakeholder, even without the consent of the original authorization holder, on grounds of public interest.

As a general comment mutual recognition can either be confined to the assessment performed by the reference MS, or expanded to the actual approval or label of the plant protection product. The latter, even if only foreseen on a voluntary base, will help in the exchange and promote the harmonization of risk management strategies.

2.2. Substitution principle and comparative assessment

An active ingredient satisfying certain hazard criteria will be classified as a candidate for substitution and its national approvals will be subject to a comparative assessment with other plant protection products or other plant protection practices, calling for a clear advantage, even economic or practical, of its use to be demonstrated. In addition mutual recognition of plant protection products containing such an active ingredients could more easily be rejected by the competent authorities of MS.

The criteria for the classification of the active ingredients address many of the concerns regarding the use of plant protection products for which ambiguity arises due to the absence of consensus regarding the specification of their potential danger. Possible endocrine disrupting properties, the prospect of developmental neurotoxic or immunotoxic effects, borderline environmental acceptability and intrinsic hazard based properties constitute some of the areas covered by the substitution principle.

[9] Council doc 11119/8/2008

Together with the classification for low-risk active ingredients and the derogation for basic substances, a gradation of the active ingredients allowed for use in plant protection products will be possible, providing a handy solution and a sustainable future alternative for low risk production models like organic farming.

In the European Parliament first reading Decision the approval of a candidate for substitution is allowed only for one time and restricted to five years (half the time for regular approvals of active ingredients). Such a clause downgrades the fundamentals of substitution and comparative assessment, as criteria for substitution become latent approval criteria, and the novel learning process of comparative assessment gets apparently stillborn.

2.3. Record-keeping and pesticide passport

The aforementioned proposed Regulation regarding the statistics of plant protection products is further proof that the need for record keeping is acknowledged from the beginning of the process for the transformation of the plant protection products legislation, since traceability is of paramount importance for establishing liability for improper use of plant protection products and controlling the market of agricultural commodities.

In the European Parliament first reading Decision the concept of a pesticide passport was introduced for any agricultural product put on the market. The obvious philosophy behind this proposal is the improvement of consumer awareness and even vigilance, a prudent and tenable argument, which unfortunately under some pragmatic circumstances, is very likely to be hampered by insuperable obstacles at implementation, and even distorted in market practice allowing for undue manipulation of consumers.

2.4. 'Cut-off' approval criteria

Risk assessment and management through mitigation measures is the cornerstone of Dir. 91/414. The Regulation proposed to replace Dir. 91/414 introduces a fundamental difference by adopting hazard based criteria.

The feasibility of such a volte-face is not based on agreed scientific principles. The main argument is a moral one and relates to augmenting and influential concerns by certain groups of European citizens regarding the per se use of hazardous pesticides.

On the other hand it is crucial to point out that many active ingredients approved as safe, according to current scientific knowledge in the context of Dir. 91/414, will have to be withdrawn under the proposed hazard based criteria.

By some of the new criteria a zero tolerance is introduced for certain intrinsic hazardous properties, by some others a zero or 'negligible' exposure of humans is sought for.

In the Council Common Position cut-off criteria apply to all substances under the scope of the proposed regulation (active ingredients, safeners and synergists).

As far as the impact on human health is concerned:

2.4.1. **Mutagenic** properties (M), classified according to Dir. 67/548/EEC[10] as categories 1 or 2, were introduced by the original Commission Proposal as cut-off criteria, with the possibility for approval only if negligible exposure is possible. The European Parliament first reading decision proposed also to incorporate the need for a review of the scientific literature, prospective changes in the classification and a schematic definition of 'negligible' exposure during use and consumption. The Council Common Position accepted in principle all the proposals and went a step further by excluding the possibility for negligible exposure.

2.4.2. **Carcinogenic** (C) and **Toxic for Reproduction** (R) properties are dealt with in the same way like Mutagenic properties, except from the fact that negligible exposure is possible but also defined: during use following the suggestions by the European Parliament, and for residues a default value set in Reg. 396/2005 is used instead of the wording proposed by the European Parliament.

2.4.3. The **Endocrine Disrupting** (ED) potential of a substance is dealt with in the same way like Carcinogenic and Toxic for Reproduction properties, but there is a fundamental difficulty and much ambiguity on the impact of such a measure. Wording proposed by the European Parliament over embryonic, childhood and combination effects, is not encompassed in Council Common Position. The difference from CMR properties is that there are no commonly agreed guidelines or procedures to determine an endocrine disrupter or related adverse effects.

2.4.4. Developmental **neurotoxic** or **immunotoxic** properties, used as criteria for candidates for substitution in the original Commission Proposal are upgraded to 'cut-off' criteria by the European Parliament first reading Decision, but are not encompassed as such in the Council Common Position.

Table 2: summary of 'cut-off' criteria regarding human health

HUMAN HEALTH 'cut-off' criteria		
Original Proposal	**European Parliament**	**Common Position**
		M 1,2
CMR 1,2	**CMR** 1,2	**CR** 1,2
Negligible exposure	Negligible exposure	Negligible exposure
	(defined)	(defined)
	Literature review	Literature review
	Prospective changes	Prospective changes
ED	**ED**	**ED**
Negligible exposure	Negligible exposure	Negligible exposure
	(defined)	(defined)
	Literature review	Literature review
	Embryonic& child	
	exposure	
	Combination effects	
	Neurotoxic	
	Immunotoxic	

CMR: carcinogenic, mutagenic, toxic to reproduction

[10] OJ 196, 16.8.1967

As far as fate and behaviour in the environment is concerned, the European Parliament first reading decision proposes also to apply to 'transformation products or residues', a wording used neither in the original Commission Proposal nor in the Council Common proposal:

2.4.5. The definition of 'cut-off' criterion of a **Persistent Organic Polluter** (POP) is almost identical in the original Commission Proposal and the Council Common Position. The European Parliament first reading Decision calls also for further, undefined but 'sufficient' evidence for persistence, as well as 'indicative' monitoring data for bio-accumulation, to be used. In addition, further reduction of indexes (BCF) used for assessing bio-accumulation is proposed.

2.4.6. The definition of 'cut-off' criterion of a **Persistent Bioaccumulative and Toxic** (PBT) substance is identical in the original Commission Proposal and the Council Common Position. The European Parliament first reading Decision calls also for further, undefined but 'sufficient' evidence for persistence, as well as undefined evidence of 'high bioaccumulation in other species' or 'indicative' monitoring data for bio-accumulation, to be used. In addition, further to classification as Carcinogenic or Mutagenic categories 1 and 2 and Toxic for Reproduction categories 1, 2 & 3, the European Parliament first reading Decision proposes to consider classification as either Carcinogenic or Mutagenic category 3, as fulfilling the Toxicity criterion.

2.4.7. The definition of 'cut-off' criterion of a **very Persistent and very Bioaccumulative** (vPvB) substance is identical in the original Commission Proposal and the Council Common Position. The European Parliament first reading Decision calls also for further, undefined but 'sufficient' evidence for the very persistent criterion (and implies that mere 'evidence' of the persistence thresholds is sufficient), as well as data from aquatic species and undefined evidence of 'high bioaccumulation in other species' or 'indicative' monitoring data for the very bio-accumulative criterion, to be used.

As far as ecotoxicology is concerned:

2.4.8. The European Parliament first reading Decision incorporates a new 'cut-off' criterion regarding **bee toxicity** ['Hazard Quotient' (HQ) less than 50'], that is not encompassed in the Council Common Position.

Table 2: summary of 'cut-off' criteria regarding fate & behaviour and ecotoxicology

FATE & BEHAVIOUR 'cut-off' criteria		
Original Proposal	*European Parliament*	*Common Position*
POP	Metabolites& residues	**POP**
PBT		**PBT**
vPvB	'Sufficient' evidence	**vPvB**
	Monitoring data	
	POP	
	Index (BCF) reduction	
	PBT	
	CM3=> **T**	
	vPvB	
ECOTOX 'cut-off' criteria		
Original Proposal	*European Parliament*	*Common Position*
	Bee toxicity	

POP: persistent organic polluter
PBT: persistent bioaccumulative toxic
vPvB: very Persistent very Bioaccumulative

3. IMPACT ANALYSIS REGARDING 'CUT-OFF' CRITERIA

An impact analysis is expected to provide a reliable account of real impacts both positive and negative. Unfortunately no such comprehensive attempt has been made so far regarding the proposed amendment of Dir. 91/414. Commission's impact assessment[11] came too early in the process and mainly reflected on the outcome of possible scenarios for policies that needed to be addressed. Approval criteria, including 'cut-off' criteria, are only mentioned once and never dealt with.

Ad hoc forecasts on the accumulated implications on an already battered European crop protection sector, is the obvious reason why it is deemed crucial for an impact assessment of 'cut-off' criteria to be carried out. At a very minimum we should at least be able to determine the number of active ingredients affected by their implementation.

As far as further negative implications are concerned, their assessment can be far-reaching and more revealing. At national level, or 'zonal' in terms of comparability of agronomic conditions and uses of plant protection products, the withdrawal of registered uses should also be predictable, and the magnitude of the effect on the productivity of certain crops can then be roughly estimated *in situ* by experts knowledgeable about the actualities of crop protection and crop production. Furthermore the impact on associated upstream and downstream industries, rural-dwellers and economy, food security as well as consumer safety, and the wider economy should also be taken into account.

It is true that in recent years, the introduction of varieties of genetically modified (GMO) arable crops with build in potential for crop protection, made it possible to avoid a number of pesticide's applications. On the other hand many European citizens and certain MS raise their concern over the uncertainties of their use. It is notable that GM varieties also require use of pesticides, either to help them establish in a weed free environment (i.e. glyphosate ready crops) or to protect them from other pests and enemies (i.e. a crop resistant to insects also has to be protected against fungal diseases and weed competition). It is also true that for non arable perennial crops commercialization of genetically modified varieties is neither feasible nor anticipated. For all the above limitations, GM technologies can only provide part of the solution for integrated pest management.

3.1. Number of substances lost

Serious methodology limitations generated by the different approaches regarding the extent of the 'cut-off' criteria, the ambiguity of some of the definitions and the pool of active ingredients considered, give rise to many interpretations and different results regarding the number of active ingredients affected.

The Swedish Chemical Agency (KEMI – competent authority for pesticides) eloquently entitles its assessment, from September 2008, as the: 'Interpretation in Sweden of the impact of the "cut-off" criteria[12]', and confines the number of active ingredients, screened only against 'cut-off' criteria of the Council Common Position, to 271, due to the fact that 'pending new substances and the substances from stage 4 not yet included in Annex I were not examined' and

[11] SEC(2006) 931.

[12] KEMI Swedish Chemical Agency 'Interpretation in Sweden of the impact of the "cut-off" criteria adopted in the common position of the Council concerning the Regulation of placing plant protection products on the market (document 11119/08)'.

also 'substances withdrawn voluntarily under Commission Regulation 1095/2007[13] but remaining on the market until 2010 are not included in this assessment'. Methodology assumptions used are 'based on the formerly applied national criteria and principles' over the interpretation of 'criteria related to identification of active substances in plant protection products as ED, PBT/vPvB or POP'. From 23 active ingredients falling under the 'cut-off' criteria (8% of active ingredients assessed) 16 are eliminated in conformity with criteria that require interpretation. No further, agronomic or other, impact is assessed. A final conclusion is reached that "cut-off" criteria will 'accelerate the peer review process of the actives substances and at the same time achieve a satisfactory level of protection of human and animal health and of the environment'.

Pesticides Safety Directorate (PSD 2008) of the UK, also performed an "assessment[14] of the impact on crop protection in the UK of the 'cut-off criteria' and substitution provisions" as a 'supplement to the regulatory impact assessment'. Due to the fact that this report was published in May 2008, the active ingredients are screened against the criteria of the original Commission Proposal, but also against the criteria adopted in the European Parliament first reading Decision. The number of active ingredients evaluated is 286, excluded were: 'substances which are likely not to be included in Annex I and may be withdrawn immediately, as a result of the procedure in Commission Regulation 1095/2007; substances on list 4 of the review programme; new active substances not yet included in Annex I'. Methodology assumptions were once again required for all criteria except CMR. For Endocrine Disruptors 'Commission sponsored reports[15] for the Community strategy on endocrine disruptors' as well as 'a report published by the Danish Ministry of Environment' and 'in one case information from a DAR' were used. Regarding the PBT criterion it is highlighted that 'the OECD Working Group Pesticides is to develop guidance on evaluation of PBT substances[16]'. The definition of 'negligible exposure' was also adding to the confusion. As a general remark Pesticides Safety Directorate felt obliged to declare that 'some of these criteria are not well defined and it is inevitable that, in analysing nearly 20 different criteria for nearly 300 substances, there is scope for different interpretations', the fact that the task undertaken by Pesticides Safety Directorate included also the criteria from the European Parliament first reading Decision, and, from both texts, the substitution criteria, make that remark self evident.

The number of substances falling under the 'cut-off' criteria in the Pesticides Safety Directorate assessment is 46 for the original Commission proposal and 118 for the European Parliament First Reading Proposal, out of the 286 evaluated. Endocrine Disrupting potential was assessed using a broad interpretation of the wording from both texts.

Following the Council Common Proposal, Pesticides Safety Directorate reiterated the position that: 'provisions in the common position for potential endocrine disrupting substances in humans are ambiguous' and 'restricted interpretations of these provisions' 'underestimate their potential impact'. The reservation regarding the definition of 'negligible exposure' seems to be addressed through the definition in the Council Common Position. So, as Pesticides Safety

[13] OJ L 246, 21.9.2007.

[14] Pesticides Safety Directorate (PSD) 'Assessment of the impact on crop protection in the UK of the 'cut-off criteria' and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of plant protection products in the market' May 2008.

[15] Groshart Ch., Okkerman P.C. 'Towards the establishment of a priority list of substances for further evaluation of their role in endocrine disruption- *preparation of a candidate list of substances as a basis for priority setting'* BKH Consulting Engineers, Delft The Netherlands 2000.

[16] OECD Risk assessments of persistent, bioaccumulative and toxic pesticides. http://www.oecd.org/document/10/0,3343,en_2649_34383_31951370_1_1_1_1,00.html.

Directorate proposes, drafting of the text for ED criteria 'in such a way that its legal scope and therefore its impact can be assessed with reasonable certainty and agreed to be acceptable before the Regulation is voted' seems to be a reasonable solution.

As a conclusion to the number of substances affected by 'cut-off' criteria it is safe to assume that the main uncertainty factor is the interpretation of endocrine disrupting properties. Because Pesticides Safety Directorate based their assessment mainly on a European report sponsored by the Commission their findings acquire more leverage.

3.2. Impact on specific crops:

3.2.1. Arable crops

Arable crops are the cash crops of northern Member States. From the late '70's introduction of chemical solutions for some of the fungal diseases and weeds made it possible for new crops or crop seasons to produce yields that attained a world high and contributed to food self efficiency of the continent.

3.2.1.1. Cereals

Winter wheat is particularly susceptible to the fungus *Septoria tritici* with possible yield loses of up to 50% under high disease pressure. The systemic fungicide family of triazoles has proven to be a reliable component for integrated control of the disease. Their endocrine disrupting properties will presumably lead to their withdrawal under a *per se* interpretation of the 'cut-off; criteria and make the outcome of commercial wheat production unpredictable and thus unprofitable. Weed control will also be hampered as persistent weed species which are known to develop resistance against pesticides (black grass, Italian rye grass) will no longer be controlled by some of the most efficient plant protection products. In a report from Nomisma (2008)[17] the overall EU effect on wheat production is assessed as a reduction of almost 30% in yield and loss of self sufficiency (from the current 104% to a possible 70%) by the year 2020. In a report from Spruitjt J. *et al* (2008)[18] the impact in the Netherlands on wheat production and revenue from strict 'cut-off' criteria as proposed in the European Parliament first reading Decision will reach 18% and 36% respectively, whereas Council Common Position 'cut-off' criteria is not expected to have any adverse impact. Based on the aforementioned report by Pesticides Safety Directorate, Clarke J. *et al.* (ADAS 2008)[19] produced an impact analysis on a number of important crops for the UK and, unlike the situation in the Netherlands, a severe impact on yield and revenue is foreseen, even if only the Commission original Proposal is adopted. Yield reduction is calculated in a range between 26% and 62% for the most severe 'cut-off' and, restricted by approval time limit, substitution criteria proposed by European Parliament, possible impact on revenue is allocated to weeds, pests and diseases starting from a marginal <1% for insects (as colder climates do not encourage the presence of certain insects) and reaching 70% for weeds. A report by Adenäuer M. and Witzke H-P. (Eurocare 2008)[20] takes the

[17] NOMISMA 'European agriculture of the future, the role of plant protection products' Bologna, January 2008.

[18] Spruijt J., Spoorenberg P., Vermeulen T., Beerling E., Roelofs P., Heijerman G., Smit B., Veen H., Meer R., Helming J., Bunte F., Galen M., Tijink F. 'Impact EU-Gewasbeschermingsverordening, Economische impact van de voorgestelde cut-off criteria voor een aantal Nedferlandse gewassen' Praktijkonderzoek Plant & Omgeving Wageningen Oktober 2008.

[19] Clarke J., Gladders P., Green K., Lole M., Ritchie F., Twining S., Wynn S. 'Evaluation of the impact on UK agriculture of the proposal for a regulation of the European Parliament and of the council concerning the placing of plant protection products on the market' ADAS 2008.

[20] Adenäuer M., Witzke H-P., 'Additional constraints for plant protection - Price impacts on European agricultural markets' EuroCARE GmbH, 53123 Bonn, October 2008.

findings of the ADAS report further by investigating the economic impacts of weed reduction. Their conclusion is that the EU will become a 'net importer' and wheat prices, depending on the severity of approval criteria in all, will rise from a minimum of 20% to a possible of 69%. Finally a study by Rickard S. (Cranfield University, September 2008)[21], based on the pervious set of reports regarding the UK, reflects on the implications to the wider economy. An apparent negative impact on upstream and downstream industries is envisaged. The consumer will also be affected by not being able to have secured access to reasonable 'price, choice and quality of food'.

Table 3: Adenäuer M. and Witzke H-P. (Eurocare 2008)

EU 25 market prices (€/t)				
	Baseline	Scenario 1 COM exclusion	Scenario 2 EP exclusion	Scenario 3 EP substitution
Wheat	111	133	156	187
		20%	40%	69%
Potatoes	104	125	139	165
		19%	33%	58%

3.2.2.2. Potato

Potato is another major arable crop dealt with in the reports regarding potential impacts of proposed new regulation for plant protection products. In the study from the Netherlands a remark is made concerning the possibility for 'Long-term effects like increasing pesticide resistance and increasing nematode populations', that overshadows any assessment carried under the current situation regarding these pests, as nematicides are the prime targets of most of the 'cut-off' criteria. Even so a crop loss ranging from 7% to 15% for seed potatoes and 9% to 20% for ware potatoes is foreseen, generating an economic loss between 13% and 31%. In its report Pesticides Safety Directorate states that no plant protection product will be available for important pests like Colorado beetle and *Liriomyza huidobrensis*. Resistance management for devastating fungal diseases, like late blight (*Phytophora infestans* is very likely to develop resistance due to potential for sexual and asexual reproduction) will be in danger because of loss of multi-site mode of action fungicides. Crop rotation to control potato cyst nematode (PCN) will be severely elongated, 'probably in excess of 10 years', and 'yields severely reduced with pressure for PCN-free land (scarce)'. Safe storage of potatoes will become 'unviable', resulting to an 'unacceptable loss of quality' an eventuality especially affecting 'potatoes stored for processing (crisps and chips)'. To produce virus free seed potatoes will be 'unlikely' without insecticides with 'knock-down' effect minimal number of insect vectors, not controlled by less efficient insecticides, can spread the disease and taint the whole production. Weed control with 'only limited options remaining' has an impact 'primarily on yield' as 'yield losses attributable to weeds can be very high, with some research citing from 36 to 54%'. In the ADAS (2008) report yield reduction is calculated in a range between 22% and 53%, and revenue loss can be as high as 76% depending on the crop protection problem. In the Eurocare (2008) report it is stated that the position of the EU as a net importer of potatoes will be 'reinforced' and prices will soar ranging from 19% to 60%. In the study from Garfield University a 'doubling' of the farm-gate price for potatoes is foreseen.

[21] Rickard S., 'WHAT PRICE PROTECTION? An Economic Assessment of the Impact of Proposed Restrictions on Crop Protection Substances' Cranfield University School of Management September 2008.

3.2.2.3. Oilseed rape

Regarding oilseed rape it is worthy to mention an illuminating example that highlights the need for adequate crop protection solutions. During an EPPO (European Plant Protection Organization) Working Party[22] (Lisbon, 2008-05-22), Udo Heinbach from Julius Kühn Institut in Germany analysed a severe case of a pyrethroid resistant pollen beetle that decimated production with losses of up to 80% in 2006. An outbreak that was only possible to be contained by using organophosphate insecticides. While Pesticides Safety Directorate in its report, assumes 'significant' yield losses for oilseed rape due to non-approval of potential endocrine disruptors, as the crop will be left without 'any fully effective compounds, for any of the major diseases', each one of which can 'reduce yields by up to 50%'. Weeds have also amounted to a serious problem for oilseed rape after many herbicides were withdrawn under Dir. 91/414, the example cited is that of cleavers with 'fewer than 5 plants/m² can result in more than 4% admixture and expensive cleaning', Pesticides Safety Directorate also reports that 'control of black-grass in oilseed rape would be without a solution', and remaining herbicides will render spring oilseed rape an unviable crop. In the Eurocare report yield reduction in oilseed rape is calculated in range from 10% to 30% according to different 'cut-off' scenarios.

3.2.2.4. Beet

Sugar and fodder beet are expected to suffer from loss of soil applied pesticides against the soil complex of insects, root and crown diseases. The Dutch study predicts a reduction of production for sugar beet in the range of 10% to 36% and an anticipated revenue downfall of 18% to 68%, while under certain presumptive circumstances 'farmers' income from sugar beet growing will disappear and also the returns in all other parts of the Dutch sugar chain'. Another report for sugar beet by Thomsen J.N. (2008)[23] from NBR (Nordic Beet Research Foundation) predicts that in Denmark, a MS already implementing 'strong regulation on plant protection products and active ingredients' and were 'limited numbers of active ingredients are available for use in sugar beets', original Commission Proposal 'cut-off' criteria will 'lead to lower profitability for the Danish beet growers' and 'higher variation in yield and profitability between years' as alternatives are 'less effective' and 'not available under Danish conditions at the moment'. Regarding the effects from the European Parliament first reading Decision NBR (Nordic Beet Research Foundation) suggests that crop sustainability can only be possible through 'substantial increase on price and products', otherwise 'production would not continue', due to the fact that 'weed control would become significantly expensive and as difficult as 40 years back, including expensive and in many cases not available hand labour', there will be 'no available insecticides for foliar control' and 'loss of seed treatment products both in terms of insecticides and fungicides would put adequate plant establishment at a significantly high risk'. Finally NBR (Nordic Beet Research Foundation) concludes that 'production efficiency will significantly be reduced and consequently community supply'. Pesticides Safety Directorate in its report agrees with the previous findings for sugar beet and reports possible losses by certain pests to be as high as 30% or even 50%. Like in potatoes weed control will also be less efficient. In the Eurocare 2008 study yield reduction, depending on the severity of the criteria, is calculated between 10% and 30%.

[22] EPPO workshop http://archives.eppo.org/MEETINGS/2008_conferences/active_substances.htm.

[23] Thomsen J.N. 'Impact on available plant protection products in sugar beets in Denmark of the 'cut-off criteria' and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of plant protection products in the market' NBR Nordic Beet Research Foundation, 2008.

3.2.2. Fruits and Vegetables

Unlike processed or starchy raw agricultural commodities, commercial standards and consumer habits render fresh fruits and vegetables very susceptible to damage from pests and diseases, as even cosmetic damage will rapidly devalue their market potential. Their tender and succulent nature makes them prime targets for insects and diseases, while weed control is crucial because of the competition for water and nutrients. Non chemical weed control is costly, labour intensive and frequently leads to soil erosion.

3.2.2.1. Fruiting crops

In the introduction the current situation of uses for minor fruiting crops in France is graphically presented. Data originates from a joint study of DGAL/SDQPV and Ctifl (Sous Direction de la Qualité et de la Protection des Végétaux/ Services Régionaux de la Protection des Végétaux and Centre technique interprofessionnel des fruits et légumes) and is reported by FNPF[24] (Fédération National des Producteurs de Fruits). Major fruiting crops like apples and peaches may not be faced today with an unsolved crop protection situation but already in many situations only few solutions are available. The following table presents the anticipated impact of the original Commission Proposal and the European Parliament first reading Decision on the number of unsolved crop protection problems for fruiting crops in France.

Table 4: FNPF 2008 (analysis by Centre technique interprofessionnel des fruits et légumes)

Predicted impacts on fruiting crops in France

CROPS	CURRENT NUMBER of USES	COMMISSION CRITERIA		EUROPEAN PARLIAMENT CRITERIA	
		no solutions (number & %)	few solutions (number & %)	no solutions (number & %)	few solutions (number & %)
Apple	78	4 (5%)	24 (30%)	21 (27%)	16 (20%)
		28 (35%)		**37 (47%)**	
Raspberry	15	1 (7%)	8 (53%)	5 (33%)	5 (33%)
		9 (60%)		**10 (66%)**	
Blackcurrant	17	2 (12%)	10 (59%)	12 (71%)	3 (17%)
		12 (71%)		**15 (88%)**	
Almond tree	21	**6 (29%)**	UNKNOWN	**9 (43%)**	UNKNOWN
Chestnut	11	**5 (45%)**	UNKNOWN	**6 (54%)**	UNKNOWN
Hazel tree	18	8 (44%)	6 (33%)	12 (67%)	3 (17%)
		14 (77%)		**15 (83%)**	
Walnut tree	14	1 (7%)	5 (35%)	2 (14%)	5 (35%)
		6 (42%)		**7 (50%)**	
Peach	52	3 (6%)	24 (46%)	23 (44%)	22 (42%)
		27 (52%)		**45 (86%)**	
Apricot	32	3 (9%)	14 (44%)	16 (50%)	7 (21%)
		17 (53%)		**23 (71%)**	
Cherry tree	22	**1 (4%)**	UNKNOWN	**7 (32%)**	UNKNOWN
Plum tree	30	**0**	UNKNOWN	**5 (17%)**	UNKNOWN

[24] Fédération nationale des producteurs de fruits, note, 'synthese des consequences sur la production fruitière du projet du règlement européen revisant la directive 91/414' (09/2008)

It is evident that major crops will be affected and minor crops may become unviable. In the report from France 'the abandonment of certain productions' is foreseen, notably hazelnut, while for peach 60% of production attained by certain seasonal varieties will perish. Even under Commission original Proposal the apricot production along the Rhone valley (50% of French production) will be in peril. Even apple farmers will face an unbearable reduction of their profit that will render 'apple production non profitable'. For minor fruiting crops speculations are gloomy as they will add to the deficiencies of the current condition. In such a context, the foreseen, by the proposed Regulation, policies in favour of minor crops may well have dubious results. If no use is registered for a major crop then it will be impossible to register a similar one for a minor crop. The same possibility exists for all the groups of agricultural products like vegetables, ornamentals and others.

Olive is a crop synonymous with the south of Europe and its products, olives and olive oil, are perceived as national diet emblems by south MS, while extensive olive groves cover picturesquely large parts of the rural country preventing erosion in the sloppy terrains of southern Europe, setting the background for a profitable tourist industry, while providing an extra income to rural areas, that is inevitably labour intensive during harvest time, which takes place in slow tourist seasons, but can be maintained and protected only by very efficient means of crop protection around the year. Certain pests and diseases can reduce yields and quality of the produce, while weeding is necessary for the availability of water and nutrients as well as the accessibility of the groves. Implementation of the 'cut-off' criteria from the Commission original Proposal will make it impossible to successfully alternate mode of actions against the olive fly and also fungal diseases will be left without solutions. The possible abandonment of the crop due to failure of production to at least compensate for the required labor will have a cascade effect to rural environment, agricultural and even tourist revenue for rural economies. The same can be anticipated for areas with citrus groves, a crop for which even only under the Council original Proposal, mites will not be able to be controlled and for various fungal diseases there will be a very restricted and inadequate array of active ingredients

3.2.2.2. Vegetable crops

In indoor vegetable production (greenhouse) integrated techniques are widely used to minimize the use of pesticides. This is especially true for insects were solutions offering a mechanical protection (i.e. insect nets), or the use of other beneficial arthropods are in every day practice. The 'drawback' is that in south MS (where greenhouses are more cost effective, by mainly being less energy demanding having a minimized CO2 footprint) where vegetable crops are endemic and even have a seasonal window of opportunity for outside production, and minimization of input costs and market price, their enemies are also endemic and abundant. Furthermore commercial vegetable production is by definition a monoculture, where appropriate crop density, for outdoor and indoor production, and the leafy nature of vegetables create a habitat that allows the smallest number of insects or levels of infection to rapidly augment beyond any non chemical control. Also the possibility for polycyclic diseases and many overlapping generations of pests are the perfect background for development of resistant strains and cross resistance development if only a handful of pesticidal modes of action are available. It is evident that the ramifications of any of the 'cut-off' criteria for vegetables will be devastating, rending their commercial production precarious and therefore unprofitable.

3.2.3. Ornamentals

Just like fresh vegetables ornamentals are by definition commercialised flawless and cosmetic damage is the actual damage. So it is not surprising that the Dutch study predicts a devastating revenue loss for rose and chrysanthemum (44% and 62% respectively) just by applying Commission original Proposal 'cut-off' criteria, European Parliament first reading 'cut-off' criteria will severely diminish production. The same result is anticipated for the emblem of the Netherlands the tulip bulb and also for ornamental shrubs. For any of the 'cut-off' criteria the calculated increased cost will annihilate and even surpass any profit.

3.2.4. Grapes

Similar conditions apply for fresh fruits but also grape vines. Integrated Pest Management provides a lot of non chemical solutions and practices that can reduce pesticide use, but those crops coexist in nature with well adapted natural enemies, who can use an occasional favourable meteorological or other regional background to infest in numbers and overcome any non chemical protection method used. Actually even in organic farming certain pesticides are used. The truth is that when evaluated against the risk based criteria of Dir. 91/414, some pesticides allowed for organic farming, failed to demonstrate a safe use and were therefore withdrawn. Nicotine and rotenone were two of the few insecticides allowed for use in organic farming, but their Notifiers respectively did not adequately supported or withdraw their notification. For copper compounds, even if included in the Annex I of Dir. 91/414, their doses will have to decrease leaving an irreplaceable void in organic farming. It has to be noted that under the Bee Hazard criterion of the European Parliament first reading Decision cooper compounds will be withdrawn altogether.

3.3. Food security

In a working paper by Witzke H. *et al.*[25] (Humbolt University 2008) regarding 'Global agricultural market trends and their impacts on European Union agriculture', the need for Europe 'to take responsibility to significantly contribute to world food security' by increasing its 'overall agricultural productivity on the available agricultural land' is emphasized. World food prices will presumably continue to rise and 'fluctuations of agricultural world market prices are likely to be higher in the future', because of 'continued growth in world population' and 'the sustained growth in per capita incomes in developing and newly industrialised countries, with corresponding increase of per capita food consumption', one can only speculate the added value to such a scenario by a diminishing production of the European farming sector. Cost and insufficiency of land and labour resources are in no position to compensate the expected yield losses.

Oerke E-C.*et al.*[26] (1994) calculated the worldwide losses of the attainable yield for the 'eight principal food and cash crops, in the period 1988-1990' to 42.1 % with crop protection, and a soaring 69.7% without crop protection. EU farmers at that time were able to achieve the world optimum efficacy of 61%, whereas N. America and Oceania where far behind with 44% and 'Other regions' managed only to obtain 39%. Such is the performance of crop protection upon which European food efficiency is built upon. Sustainability of agricultural production in Europe will therefore be in peril if crop protection is doubtful due to lack of alternatives.

[25] Witzke H., Noleppa S., Schwarz G. 'Global agricultural market trends and their impacts on European Union agriculture' Working Paper 84 (2008) Humboldt University of Berlin, Germany.

[26] Oerke E-C., Dehne H-W., Schönbeck F., Weber A., 'Crop production and crop protection-estimated losses in major food and cash crops' Elsevier 1994.

European consumers will be the first affected by any domestic shortfall in food supply. Worldwide food fluctuations generated by foreseeable or unforeseeable, climatic or geopolitical events in any part of the world would be impossible to be tempered with by an uncertain and thus flickering European food production. Exchequer funding may also be required to cover the extra cost, in the hopeful scenario of availability of food imports.

3.4. Food industry

Food industries, a pride of many MS for their quality and standards, just like consumers, will face the soaring combined cost of raw material and transportation. According to a recent Eurostat news release[27] on euro indicators (161/2008), the trade deficit for 'food and drink' for the first 8 months of 2008 was 8.5 billion €, but the Euro zone actually had a surplus of 8.1 billion €. Possible relocation of industries like mills, brewery, sugar, crisps and others will deteriorate the deficit.

3.5. Cost of Plant Protection Product – Agrochemical industries

The possibility of abandonment of certain crops or crop seasons, due to the lack of crop protection solutions and the unpredictability of production, has already been demonstrated. The impact on the rural economy is evident, yet another contributing cost component needs also to be highlighted. Market price of a Plant Protection Product is conditioned in two ways. Firstly by the presence of an equivalent PPP with the same active ingredients, and secondly by competition from other PPP with different active ingredients, but which are used for the same purpose. So a plethora of active ingredients reduces the price of a plant protection product, while the scarcity of active ingredients will inevitably create oligopolies or even monopolies.

Multinational agrochemical industries, with the necessary R&D, will be able to enlarge their share in a withering and insecure market. Market price of the remaining active ingredients will be subject to heavy transfer pricing, while their market dominance will be unchallenged and extensive. This provides the opportunity for industry to recuperate losses suffered from the withdrawal of other active ingredients, but at the expense of the European farmers and consumers.

[27] Eurostat news release/euro indicators 161/2008 'September 2008 Euro area external trade deficit 5.6 bn euro 23.0 bn euro deficit for EU27'.

3.6. Food safety

It is notable that the objective of the amendment and complement of PPP's legislation is, according to Decision 1600/2002[28] [as adopted by the 6th Environment Action Programme (6EAP)] to 'reduce the impacts of pesticides on human health and the environment, and more generally to achieve a more sustainable use of pesticides with the necessary level of protection against pests'. But in the eventuality of depending more upon imports to satisfy European food demand, it would be inevitable to expose European consumers to higher risks. Those are the constant findings from the highly regarded monitoring reports on pesticide residue in products of plant origin. In the last three consecutive reports published for 2004 to 2006[29], imported fruits, vegetables and cereals exhibit two to three times the exceedances of Maximum Residue Limits than those produced in the EU. This is primarily due to the fact that outside EU boundaries active ingredients, already withdrawn under Dir. 91/414, are still legitimately used, tipping the balance against the competitiveness of European agriculture. For example, soil insecticides like carbamates are still in use in various Mediterranean non EU countries. Further and scientifically unjustified withdrawal of active ingredients after the implementation of hazard based 'cut-off' criteria will just aggravate the situation, as it will be even more difficult to convince our trade partners of the benefits of such an approach.

Table 5: EU monitoring reports on pesticide residue in products of plant origin

Exceedances/100 samples			
Origin / Year	2004	2005	2006
EU	2.4	2.4	2.2
IMPORTED	6.8	6.5	6.4

3.7. Anticipated benefits as a result of sustainable use Directive

'The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products' are summarized in a review study, by Blainey *et al*[30]. requested by the European Parliament's Committee on the Environment, Public Health and Food Safety. An extensive array of medical, epidemiological and environmental studies, concerning relevant effects of pesticides, is presented, and a firm conclusion in favour of 'cut-off' criteria is reached. Of the many different studies, certain studies are particularly highlighted and cited in the executive summary.

[28] OJ L242,10.9.2002.

[29] COMMISSION STAFF WORKING DOCUMENT 'Monitoring of Pesticide Residues in Products of Plant Origin in the European Union, Norway, Iceland and Liechtenstein 2005' Brussels, 17.10.2007 SEC(2007) 1411, Part I.
COMMISSION STAFF WORKING DOCUMENT 'Monitoring of Pesticide Residues in Products of Plant Origin in the European Union, Norway, Iceland and Liechtenstein 2006' Brussels, 20.11.2008 SEC(2008) 2902, Part I.
COMMISSION STAFF WORKING DOCUMENT 'Report on THE IMPACT ASSESSMENT FOR A REGULATION REPLACING DIRECTIVE 91/414/EEC ON PLANT PROTECTION PRODUCTS' Brussels, 12.7.2006 SEC(2006) 931.

[30] Blainey M., Ganzleben C., Goldenman G., Pratt I. 'The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products', study requested by the European Parliament's Committee on the Environment, Public Health and Food Safety. (Ref to contract: IP/A/ENVI/FWC/2007-057/C1/SC2) September 2008.

The magnitude of the economic benefits is quantified: either by a World Bank study[31] from 2001 that estimated the burden of disease (deaths and general ill health) from agro-industrial chemicals and chemical pollution from diffuse sources in established market economies to be between 0.6% and 2.5% with a central estimate of 1.5%, or by a study conducted for the UK Pesticides Safety Directorate (PSD) by Risk and Policy Analysts[32] (RPA) regarding the potential occupational health benefits arising from withdrawal of approvals for specific active substances, and estimated 'at a lower range of £93 to £186 million in potential cancer cases avoided for spray operators only, with an upper range of £354 to £709 million in potential cancer cases avoided for the maximum exposed farm worker population in the UK, over the relevant exposure period of 30 years (RPA, 2008)'.

On the other hand, data limitations facing any researcher in this field make it difficult to grant conclusions much validity, as authors of both studies acknowledge. In the World Bank study prior to the aforementioned percentages it is stated that: 'Poisoning is the most often cited health consequence of pesticide use. Skin and eye contact during application may lead to neurological or immunological reactions ranging from irritation to serious complications requiring immediate medical assistance. Usually, such incidences arise from improper application or container disposal. In addition to occupational hazards, toxic exposure to pesticides is believed to result under particular conditions, including the repeated application of a persistent compound over a period of years near to drinking-water sources. Even under these conditions, however, at levels several times the quality standards, the resulting build-up has rarely been linked with observed or expected health problems'. In the RPA study in the paragraph following the presentation of the aforementioned study sums it up with the statement: 'The greatest source of uncertainty lies in the use of odds-ratios which reflect associations between exposure and cancer or wheeze outcomes rather than demonstrated causal relationships. It is clear from the reports by the UK Committees which review the linkages between chemicals exposure and cancer, for example, that the results of the epidemiological studies are not consistent enough or sufficient on their own to justify regulation on the basis of the associations that have been found. Thus, the estimates provided here can only be treated as potential indicators of the value of the indirect occupational health benefits that have stemmed from regulation to date or which may be associated with the future regulation of those of the case study active ingredients still in use'.

It is therefore evident that improper use and the exposure it provokes are elementary components of any adverse effect from pesticides. Expert advice and training as envisaged in the Directive for the sustainable use of pesticides, provides an opportune tool, as it will not only complement the safety attained by the risk related withdrawal of a large number of active ingredients under Directive 91/414, but will also compensate for the lack of alternatives in crop protection already sustained by conventional, integrated or even organic farm production in Europe.

[31] Lvovsky, K., et al., 'Health and Environment Strategy Papers', 2001, No1, Working Paper 24096, World Bank.
[32] RPA (Risk and Policy Analysts). Study on the Benefits of Pesticide Regulation: Final Report for the Pesticide Safety Directorate, Parts 1 & 2 (July 2008).

4. CONCLUSION

The introduction of hazard based approval criteria in the Regulation amending Directive 91/414/EEC[33] concerning the placing on the market of plant protection products (PPP) is apparently necessitated as a result of the augmenting and influential concerns of some groups of European citizens. On the other hand, a negative impact on the sustainability of European agriculture is speculated, according to various reports by competent authorities and stakeholders. Widespread ramifications are depicted as aggravating the already fragile arsenal of European crop protection, left currently at the disposal of the European farmer. This is the result of the withdrawal of almost 75% of active ingredients, accomplished through the implementation of risk based criteria provided by existing Directive 91/414/EEC. Such findings are contrary to the ones anticipated by the Commission and certain Member States in favour of 'cut-off' criteria. The contradiction can be explained by the ambiguity generated from the lack of agreed scientific principles for the definition of some of the 'cut-off' criteria, namely the endocrine disrupting potential of a substance and some environmental criteria. The European Parliament first reading Decision encompassed further 'cut-off' criteria by upgrading a number of 'substitution criteria' mentioned in the original Commission Proposal. They are also hazard based criteria and are intended to classify the approved active ingredients that pose a higher risk.

It is notable that a complement to the Regulation amending Directive 91/414/EEC 'concerning the placing on the market of plant protection products' is also proposed, in the form of the Directive 'for the sustainable use of pesticides'. Both proposals serve the combined objective of reducing 'the impacts of pesticides on human health and the environment', while securing 'the necessary level of protection against pests'. Risk mitigation is envisaged to shed from registration to the actual user level. Implementing Integrated Pest Management will bond both tiers with monitoring use data in a continuous exchange of information, for the shake of renewal and amelioration of crop protection techniques. In this context, the use of Plant Protection Products ought to be a last and justified resort. Knowledgeable decisions and precautious applications can fulfil both set objectives.

European farmers managed until now to attain world record yields that contributed to the food self sufficiency of the continent. In case the worst scenarios are confirmed, regarding the impact of 'cut-off' criteria, European agricultural economy and related upstream and downstream industries will wither and Europe will become a net importer of agricultural products. At this time, consumers will not have secured access to reasonable 'price, choice and quality of food'. No conclusive report has as yet challenged these arguments.

The actual impact of the 'cut-off' criteria will directly correlate with the scope, extent and clarity of the definitions. Rigid and agreed definitions are necessary in order to assess and balance their impact with respect to the twin objectives for reducing the impact while protecting the crops. Only then, can a conscious and informed decision be made for the benefit of all people in the EU. We must also consider that in order to achieve a sustainable and viable agriculture industry in the EU we would have to impose, from farmers and trade partners outside the EU, similar standards to provide European consumers with the safety level envisaged by the proposed legislation for pesticides.

[33] OJ L230,19.8.1991

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