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**UEAPME AMENDMENTS TO THE PROPOSAL FOR A REGULATION OF
THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING
THE PLACING OF PLANT PROTECTION PRODUCTS ON THE MARKET**

Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market

I. MODIFICATION OF DIRECTIVE 91/414/EEC

I.1. Current situation

Currently European Council and Parliament are working on a Proposal for Regulation for the modification of Directive 91/414/EEC (hereinafter, the "Proposal for Regulation").

With regard to this modification process of the Directive, it is particularly relevant for the SME plant protection sector the fact that — as it has been reiterated over the last few years — it adopts relevant measures to guarantee access to data, in accordance with international law (TRIPs Agreement, United States) and in accordance with the spirit of the Directive - Removing the legal vacuum that allows large companies that hold the data to be able to abuse their dominant position to make access difficult-. This conduct is of course clearly contrary to Competition Law but difficult to prove.

As we will see below, the proposal for modification, although it introduces important changes that come nearer to UEAPME's position, it has still some deficiencies that may consolidate and prolong the serious situation that the plant protection sector is facing since Directive 91/414/EEC came into force.

UEAPME will focus on the most relevant points which directly affect the future of SMEs, and which -if not eliminated- will result in the elimination of SMEs from the plant protection sector.

In general, there are two sections of the Proposal for Regulations that affect European SMEs most directly and seriously:

1. The proposal regulating the transitory measures in article 77, seems to exclude “**existing active substances**” and “**existing plant protection products**” from the regime of obligatory negotiation and fair compensation in the event that an agreement is not reached between the affected parties, which was only envisaged in article 59.3 for the avoidance of repeat test and studies on vertebrates.

These substances and formulated products are those that were found on the market two years after the date of notification of Directive 91/414/EEC, i.e. on 26th July 1993, **and form the major part of the business activity of our SMEs of the plant protection sector.**

2. With regard to the “**Data sharing**” regime stipulated in article 58, it is necessary to specify what would happen in the event that the parties do not reach an agreement to share the necessary data in order to obtain, renew or review an authorisation. Otherwise, the established regime will be absolutely useless for the intended purpose, and will favour the existence of abuse by large multinationals that hold the necessary data for obtaining or maintaining the authorisations that SMEs need.

Thus, it seems reasonable to impose on this situation the regime established for this purpose in article 59 to avoid the duplication of tests in vertebrates, which is based precisely on obligatory negotiation and the setting of fair compensation for the use of this data.

However, the regime established in article 59 presents a legal vacuum that could be extremely relevant, as it omits any reference to the criteria that must be used for the determination of the aforementioned fair compensation for data sharing, with the enormous discretion and legal insecurity that this generates and the possible inequalities that may be produced in practice in similar situations.

I.2. Harmful consequences for the agricultural sector arising from the application of the system proposed by the Proposal of the Regulation

The consequences of the actual situation described will be serious for agriculture (**in particular for the Mediterranean Area**), for **Plant Health**, for farmers and for the SMEs in the sector, in the terms set out below.

I.2.1. Consequences for agriculture and plant health

The effects of withdrawal of the plant protection products from the market on the fruit and vegetable crops will be notorious. It is logical to think that **there will be no defence of active substances with expired patents with a low profitability according to the multinational companies, creating phytotherapeutic vacuums**, as has been observed with the withdrawal of many insecticide products in the review programme, which **directly affect on many fruit and vegetable crops produced in the Mediterranean area**.

And so, the harmful consequences for **the Mediterranean** agriculture and **Plant Health** are, fundamentally, the following:

1. The withdrawal of active substances and their **plant protection** products for non-notification or the Decision of no inclusion, which implies its withdrawal from the market.

2. Reduction of the authorized uses for the plant protection products as result of the application of the European Directives on the maximum residue levels on vegetables and vegetable products. The review of the uses of plant protection products on certain crops means that certain uses are not maintained and no products are found to combat the pests and diseases.

3. Reduction or elimination of **plant protection** products and mixtures expressly thought to control the specific plant protection problems of agriculture that could be done to date.

4. Reduction in the offering of plant protection products on the market.

5. Phytotherapeutic vacuums will appear.

6. Resistance in plagues and/or diseases will appear, as there will not be enough plant protection products to carry out sufficient rotations.

7. Reduction in production with regard to the quantity and quality of fruits and vegetables and their final products.

8. Research and Development work carried out by SMEs on the control of plagues and diseases specific to the national territory will be eliminated.

Regarding points **5** and **6**, it is worth highlighting the fact that a phytotherapeutic vacuum is produced, when another chemical or non chemical system does not exist, for the control of plagues or diseases, will directly result in the reduction of the production and/or in the quality of the final product and, therefore, in a reduction in income of the farmers.

Due to the withdrawal of active substances for lack of notification or due to the difficulty in passing the criteria and tests established by the application of Directive 91/414/EEC, many insecticides of particular importance in the Mediterranean agriculture have been withdrawn from the market. Within these products there is a large amount of carbamates and organophosphates.

For the control of many plagues there is no other active substance available to the already authorized current one, with a limited time for their use and with many difficulties in the application (development of new alternatives). The only possibility is to consider them as products of "Essential Use",

It must be considered that although an alternative product is manufactured or exists normally at much higher price, **the presence of existing substances in the market has a great importance for the rotation of plant protection products in order to reduce the appearance of resistance.**

1.2.2 Consequences for Generic SMEs

The main problem facing SMEs within the review programme of existing active substances is the high cost of investment which must be incurred to defend the active substances (approx. 2.4 Million € each, depending on the information needed and 600,000 € more for each of the plant protection products in their catalogue) and, as we have previously mentioned, this situation is absolutely unbearable in economic terms for the national SMEs and will force the closure of 90% of the businesses.

Apart from the high cost incurred by the defence of the existing active substances and the **plant protection** products that contain them, other factors in the SMEs also influence the difficulty in defending the active substance and maintaining the **plant protection** products on the market, such as:

1. Having a varied catalogue of products: the minimum catalogue of a SME in the sector has 60 **plant protection** products. Each **plant protection** product contains one or more active substances, with the resulting difficulty in the defence of each and every one of them and, therefore, of the **plant protection** product.
2. In the event of defence of the active substances, the community review programme tends towards their elimination, adding insecurity to the review programme and to the economic investment arising from this defence. The result is the reduction in the active substances and, therefore, of the catalogue of products of the SMEs and of the companies' profitability, which entails their closure.
3. The SMEs in the sector keep competitive in the market due to the variety of products in their catalogue more than for the volume of sales of a specific product.
4. The withdrawal of "existing active substances" from the market, as well as, the preparation of the studies necessary for the defence of an existing active substance which is not included in Annex I of the Directive weaken the economy of the SME.
5. In the event of incorporating an "existing active substance" in Annex I, and in the event of having a letter of access, the review process tends to reduce the authorized uses of the plant protection products in many cases,

something which is seen in the sector by the application of the different Community Directives on the maximum limits of plant protection residues in vegetable and products of vegetable origin and the ever more demanding environmental restrictions.

With all this, UEAPME does not wish to say that only the SMEs will be unable to defend a large number of active substances, as it is possible that the large multinational companies could be also unable to defend all the active substances they wish, due to the high economic cost it represents.

However, it is important to highlight that **the active substance defended remain in the hands of a very small number of multinational companies to whom the exclusive rights are granted for a prolonged period of time established by the data protection system, a situation which seriously affect the SMEs.**

Generally, it is also observed how **extremely difficult it is to obtain the letters of access to the active substances, as at the moment there is no legal obligation to share the test or studies required.**

At this point it is important to remember that this situation is not the result of the action of the SMEs in the market, as it's well known, at no time UEAPME tried to obtain free access to the protected data, but it demand fair access paying an equitable price adjusted to reality.

If the current draft of the Proposal will not be modified in the manner we propose the SMEs will be irremediable condemned to disappear from the market.

II. **AMENDMENTS TO THE ARTICLES**

II.1. **MODIFICATION. Article 24**

(i) Proposed wording:

“1. By way of derogation from Article 5 and Article 14 (2), an active substance complying with the criteria provided for in Article 4 shall be approved for a period not exceeding seven years, where other already approved active substances are significantly less toxic for consumers or operators or present significantly fewer risks for the environment. The assessment shall take account of the criteria laid down in point 4 of Annex II.

Such a substance is referred to hereinafter as a “candidate for substitution”.

2. Article 4(4) and Articles 6 to 21 shall apply.

3.-This article shall not apply to active substances which were on the market two years after the date of notification of the Directive.”.

(ii) Justification:

We consider that the “substitution principle” should be deleted from the Regulation proposal, regarding existing active substances -those that were on the market on 26th July 1993-, due to they are substances which has been used usually for more than 15 years and will have been subjected to a prior review by the Member States in charge of the evaluation and by the designed organisms by the European Commission that will guarantee its harmlessness.

For these reasons, it's not reasonable to establish a limitation to the duration of the authorization related to those substances.

II.2. MODIFICATION. Article 58.3

(i) Proposed wording:

*“3. The prospective applicant for the authorisation and the holder or holders of relevant authorisations shall take all reasonable steps to reach agreement on the sharing of test and study reports protected under articles 56 required by the applicant **for seeking, renewing or reviewing** an authorisation of a plant protection product.*

Where the prospective applicant and the holder or holders of the relevant authorisations of plant protection products containing the same active substance, safener or synergist cannot reach agreement on the sharing of test and study, the prospective applicant shall inform the competent authority of the Member State. The two parties shall nevertheless agree which courts have jurisdiction for the purpose of the second subparagraph.

The failure to reach agreement, as provided in paragraph 2, shall not prevent the competent authority of the Member State from using those test and study reports for the purpose of the application of the prospective applicant. The holder or holders of the relevant authorisation shall have a claim on the prospective applicant for an equal share of the costs incurred

by him, which shall be enforceable before the courts of a Member State, as designated by the parties under the first subparagraph. Those courts shall have regard to the principles in paragraph 2.

The information, tests and study reports which agreement can be reached between the parties will belong to both as co-owners of these data, once the other applicants have paid or compensated for them”.

(ii) Justification:

Article 58 of the community Proposal for Regulation correctly establishes a regime of a compulsory negotiation consisting in, with regard to those studies and tests referred to in article 56, the first informer of a plant protection product doing whatever is reasonably in his power to reach an agreement with the parties that are later interested in obtaining the authorisation regarding the sharing of the confidential information.

However, and although it is true that compulsory negotiation is one of the pillars of the position defended by SMEs for years, it is no less important that it should be necessarily accompanied by the drafting of a system that allows those situations where the parties cannot reach an agreement to be solved.

Otherwise, and bearing in mind, above all, the situation of review process of authorisation of existing active substances obliged by community legislation, the decision regarding access to all the documentation needed to maintain the validity of the authorisations would remain in the hands of the SMEs' competitors, which would completely lessen the value of the compulsory nature that this negotiation tries to impose.

And, although it is true that the system allows individual negotiation between the holder of the necessary technical data (main holder) and the formulator who does not have it and needs the substance, it is also true that general objective parameters are not established for that individual negotiation that guarantees access to the information in reasonable conditions nor is there a specific procedure established for cases of difficult agreement, whether submittance to arbitration or creating an authority that resolves disputes, and nor do we find any provision regarding the possible criteria to be applied for establishing a fair, reasonable and proportionate compensation in favour of the holder.

Even more when it refers to the negotiation between competitors where one of them has a dominant position and in which, if it ends with the refusal of access, the formulator cannot turn to any subsidiary remedy that allows it to continue its activity.

With this lack of provision within the regulation ends any possibility of SMEs to enter into the system in equal conditions compare with multinationals. As a result, in practice, only multinationals with large implementation and resources have become notifiers of active substances. And, consequently, the activity of small manufacturers with less implementation goes on the line to completely depend on those who could eliminate them from the market. Without doubt, the legislation thus protects the commission of abuse of a dominant position.

In short, with the introduction of a system based on the compulsory data sharing and in setting a fair, reasonable and proportionate compensation by an impartial public authority — whether arbitration or court —, not only would it avoid the useless and expensive repetition of experiments and analysis that are essential for obtaining or reviewing the authorisation of a plant protection product, but also it would be clearly beneficial for competition and SMEs, which could continue with its activity in terms adjusted to the rules of the market, without the harm caused by the lack of provisions such as those commented.

As can be seen, and with the aim of respecting the current draft as much as possible, UEAPME proposes to set out the same system established in Article 59 of the Proposal for the studies and tests relating to vertebrates, but expanding it to all documents which Articles 56 and 57 refer to as necessary for the granting, renewal or review of authorisations.

Finally, the original text does not expressly recognise the fact that the party that has paid compensation for the data becomes co-owner of it from that moment on. It is for this reason that with the last paragraph added to article 58.3 any possibility is removed of it being considered that the compensation effectively paid only gives a right to a mere rental or temporary grant of data.

II.3. ADDITION. New article 58.4

(i) Proposed wording

“4. The decision referred to the determination of an equal share of the costs related to data sharing and avoidance of duplicative testing shall take the following elements into account:

- the cost of generating the information discounted to reflect the period of protection remaining;

- ***the cost of assembling the dossier submitted to achieve the inclusion of an active substance in Annex I;***
- ***a compensation for the risk of supporting the inclusion of an active substance in Annex I. Under no circumstances will this value exceed 0.2% of the total amount of the studies to be compensated***
- ***eventual compensation already paid to any of the parties concerned and the amounts thus paid.***
- ***the costs of the process, which will be divided equally between the data holder and the applicant in each case.***
- ***The value of the National or Zonal market share of the following applicants, obtained from the volumes of sales that the product achieves in the market for which application for access to data is made.***
- ***The remaining time until the expiry of the period of data protection from their date of receipt by the rapporteur Member State commissioned with the evaluation of the substance”.***

(ii) Justification

Due to the complexity and specificity of the field in question, it seems reasonable that the legislation facilitates the task of Courts and Tribunals providing them with evaluative criteria that allows them to set the “fair compensation” to which the legislation refers, and thus reducing, to the benefit of all the parties, the extremely wide margin of discretion that the current draft implies.

In short, the criteria proposed here fundamentally correspond to those already envisaged in the previous draft of the Regulations in the field of arbitration and which, for reasons unknown to us, have been removed from the latest version.

Similarly, we introduce as a new feature the last two parameters for evaluation that appear listed, as we understand that in order to set the compensation for the holder of protected data the market share of the requesting party should be borne in mind, as it does not seem practical for two potential requesting parties to have to pay the same amount assuming that, for example, one of them markets its products in one country only and the other, however, distributes its products throughout several countries in the European Union.

With regard to the last criteria proposed, it is based on the need that the amount that is to be finally paid takes care of the time during which the corresponding studies and tests have been carried out and, therefore,

that it considers the period of confidentiality that remains for the substance or plant protection product in each case.

In short, it would not be fair that the same amount be paid regarding a substance for which the period of confidentiality has just begun, than for another for which the protection is about to end.

II.4. MODIFICATION. Article 59.3

(i) Proposed wording

*“3. If the prospective applicant and the holder or holders of the relevant authorisations of plant protection products containing the same active substance, safener or synergist can not reach an agreement on the sharing of test and study reports involving vertebrate animals, **shall apply the procedure foreseen in Article 58.**”*

(ii) Justification

The proposed amendment aims to avoid unnecessary repetitions of that drafted, by referring to the regime of compulsory negotiation and fair compensation that we understand must be provided for in article 58.3 for all the documentation needing for the granting, renewal or review of authorisations, and not only that regarding tests and trials on vertebrates.

II.5. ADDITION. Article 77.3

“3. In the cases foreseen in paragraph 1 or paragraph 2, Article 58 shall apply.

Furthermore, where article 13 of Directive applies by virtue of these paragraphs, it shall be subject to any special rules concerning the Directive laid down in the Act of Accession by which a Member State joined the Community.”.

(ii) Justification

Certainly, we understand that any doubt must be removed regarding the effective applicability of the regime of compulsory negotiation and fair compensation established in this legislation for “existing” active substances and “existing” plant protection products, it means, those that were on the market on 26th July 1993, and that enter within the scope of application of the transitional measures established in this regulation.

In this sense, it is worth highlighting that these existing substances and products are the fundamental basis on which the business activity of SMEs in the plant protection sector has been developed for more than 30 years.

Preventing SMEs from access — always through negotiation and economic compensation — to the essential data for the maintenance of the authorisation regarding the plant protection products containing “existing active substances” would have extremely serious consequences for their business and, therefore, for their subsistence.

This would also, evidently, have repercussions in the agriculture of a large extent of Europe, upon generating plant protection vacuums resulting from the removal of essential plant protection substances and products for fighting pests that are typical of the most important crops in each Member Estate.