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UNIONE EUROPEA DELL' ARTIGIANATO E DELLE PICCOLE E MEDIE IMPRESE

REPORT FROM UEAPME ON THE SITUATION OF THE GENERIC PLANT PROTECTION SECTOR AND AMENDMENTS TO THE PROPOSAL FOR REGULATION WHICH MODIFY DIRECTIVE 91/414/EEC (DOCUMENT SANCO 10159, Rev. 0 06/04/2005) DRAFTED BY THE EUROPEAN COMMISSION

## I. INTRODUCTION

The European Commission is currently working on a Proposal of the Regulation for the modification of Directive 91/414/EEC (hereinafter, the "Proposal of the Regulation").

Facing this modification process of the Directive, it is particularly relevant for the **generic** plant protection sector that –as it has been repeatedly stated in the last few years- the necessary measures to guarantee access to data be taken, in accordance with international legality (TRIP Agreements, United States of America) and in accordance with the spirit of the Directive, filling the legal gap that allows large companies holding data to abuse of their dominant position making access to data difficult, a conduct that is clearly contrary to Competition rules.

As we will see below, the modifications proposed of Directive 91/414/EEC, although introducing important novelties that approach the position persistently defended by UEAPME, suffer from serious deficiencies, which consolidate and prolong the difficult situation of the plant protection sector since Directive 91/414/EEC entered into force, and which we have described above.

In this sense, we must refer to the relevant articles of the Proposal of the Directive which cause greater concern in the relevant SMEs sector:

- Article 30: Data protection at first inclusion of the active substance

This Article regulates the protection of confidential data in those situations of first inclusion of an active substance in Annex I of the Directive.

As it can be seen, this article includes two provisions that are particularly worrying for the sector we represent: (i) it establishes that the period of data protection will last **10 years**, from the moment in which the inclusion of the substance in Annex I occurs (art. 30.2), and (ii) that the arbitration procedure envisaged in article 38 will **not** be applied to data regarding this first inclusion (art. 30.3); and all of this independently of dealing with a "new" or "existing" active substance.

- Article 33: Data protection at first authorizations of the plant protection product

Regulation of this precept is identical to that of article 30, with the difference that in this case it refers to the first authorization of a plant protection product. Thus, it establishes the 10-year protection, as well as the exemption from the arbitration regime of article 38.

- Article 41: Transitional measures

This article refers to the transitional regime of the “*existing active substances*”, which implies that provision established in article 13 of Directive 91/414/EEC continues to be applicable. The following conclusions must be extracted from this important provision:

- (i) The new regime that the Proposal of the Directive intends to establish regarding protection and sharing of data is **not** applicable to “*existing active substances*”, that means, those that were on the market on 26th July 1993, which are precisely those that form a large part of the commercial activity of small and medium **generic** plant protection enterprises.
- (ii) The exclusion of these substances implies that SMEs cannot benefit from the compulsory negotiation and arbitration regime envisaged in articles 37 to 39 (“*Data sharing*” and “*Arbitration*”). Therefore the essential data cannot be accessed. This would allow to obtain or maintain the authorizations for manufacturing and marketing of their **plant protection** products, unless the registration holder voluntarily agrees.

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## **II. BACKGROUND: Council Directive 91/414/EEC, of 15<sup>th</sup> July 1991, regarding the registration and marketing of active substances and plant protection products**

Council Directive 91/414/EEC, of 15th July 1991, hereinafter "the Directive", regarding the registration and marketing of active substances and plant protection products was created in order to harmonise the different procedures established in Member States, which are an obstacle to exchanges in the single market, as well as with the clear purpose of protecting people, animals and the environment.

In accordance with the Directive, only those plant protection products that contain active substances included in Annex I in their formulas can be authorised. For this purpose, the system presents two different stages: one which is the competence of the Commission regarding the inclusion of an active substance in Annex I of the Directive, and the other, competence of each Member State, of authorisation of a plant protection product made from active substances included in the aforementioned Annex.

For the inclusion of the existing active substances in Annex I, a programme of work for the review of a total of 1022 active substance divided into different stages was established. With regard to the first Stage, this has been divided into two periods; one to register the active substances that were on the market two years after the date of entering into force of the Directive -26<sup>th</sup> July 1993-, known as “**EXISTING ACTIVE SUBSTANCES**” and another for the registration of active substances that were still not on the market at that time, known as “**NEW ACTIVE SUBSTANCES**”.

Regulation (EC) 3600/92 of the Commission established the first stage of work, to evaluate the first 90 existing active substances that intend to be included in Annex I. It was hoped that, later on, the new Regulations would be published every 2 years, to allow a new gradual evaluation of the active substances to be carried out. But due to the delays incurred in the evaluation of the first active substances, the remaining regulations were published between 2000 and 2004.

In accordance with the texts of the Directive and the Regulations, the producer of an active substance in Annex I must notify the European Commission of an application for inclusion of an existing active substance and defend (provide the required studies) the rapporteur Member States designated for the evaluation of each one. However, and as an exception, the European Commission decided that the evaluation of the group of existing active substances of the Third Stage should be carried out by the “Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA)” in Germany, through the “RENDER Project”, the functions of the BBA being defined in Annex VII of Regulation (EC) 451/2000.

Thus, the producer interested in the inclusion –notifier of the active substance- must submit for the consideration of the corresponding Member State a detailed dossier on the properties of the active substance so that the corresponding state or body may recommend the inclusion of the this substance in Annex I of the Directive to the Commission.

It must be highlighted that **the preparation of these dossiers is so expensive that only the large companies in the sector can meet**, as they include studies on efficiency (Directive 93/71/EEC), physical-chemical properties (Directive 94/37/EEC), toxicology (Directive 94/79/EEC), environmental impact (Directive 95/36/EEC), Ecotoxicology (Directive 96/12/EEC), analytical methods (Directive 94/46/EEC) and residues (Directive 96/68/EEC).

The evaluation procedure concludes with the decision of Inclusion or No inclusion of the active substance into Annex I. If this decision is positive, **any plant protection product containing this active substance in its formula must be re-evaluated by the competent state authorities** in accordance with the procedure envisaged in the Directive. If the decision is No inclusion, products containing this substance cannot be marketed. The active substances that do not pass the established tests or are not defended will be withdrawn from the market (and, therefore, all products that contain it) before July 2003 or 2008 depending on the stage of evaluation in which the review of a certain active substance is contemplated.

To compensate the cost of the evaluation studies of the active substance **for the large company notifier of the active substance for which inclusion has been accepted**, in accordance with that envisaged in Article 13. 3.d) of the Directive, a **supplementary data protection period of five years is granted for the exclusive rights of confidentiality** about the technical information needed to use this substance, **which is extended to ten (10) years in practice as these exclusive rights of confidentiality are maintained until the expiry of the data protection period of the plant protection product, which must be registered with the active substance in question for its inclusion in Annex I of the Directive.**

It is precisely this community provision that gives rise to the **serious situation of the plant protection sector and which only affects SMEs**, as it has been reported on numerous occasions before the European Commission, without being followed by the necessary regulatory measures.

More specifically, the problems raised by the Directive Proposal falls on the “existing active substances”, which is the most important group for SMEs as this is the main basis of their commercial activity and corresponds to those which were already marketed two years after the date of entering into force of the Directive -26<sup>th</sup> July 1993-.

Of the activities carried out in the programme of review of the existing active substances, in accordance with the public information made known by the European Commission, the following table summarises the current situation of the process which affects the existing active substances used in the sector.

**Table 1. Situation of the existing active substances review Programme established by Directive 91/414/EEC.**

Stages of community review	Situation of active substances					
	Total active subs. per Stage <sup>1</sup>	Notified	Withdrawn		Included	Still to be decided
			Not Notified	Do not meet criteria		
First	90	90	0	28	53	9
Second	149	53	96	3	3	47
Third	399	161	248	4	-	147
Fourth	384	254	112	18	-	254
Total	1022	558	456	53	56	457

In particular, out of the 1022 active substances currently affected by the Community Review Programme, at the moment only 56 (5.5%) existing active substances have passed the programme of review and have been included in Annex I of Directive 91/414/EEC, whilst 509 (49.8%) have already been withdrawn from the market. On the other hand, there is uncertainty about 457 (44.7%) active substances which are at the "still to be decided" stage.

We highlight as a **crucial** point, that the 56 existing active substances included to date in Annex I of Directive 91/414/EEC are in the hands of multinational companies which do not wish to provide access to the data required by the SMEs for the maintenance of their registers and, therefore, their marketing. In other cases multinational companies provide access to the data to SMEs at such conditions that it is almost impossible to fulfil.

Therefore, the situation is discouraging for SMEs, which are heading towards an inevitable reduction in their product catalogues with a consequent reduction in profitability, under the terms we will set out later, consequences which, in turn, will imply production plants close, and the need for workforce readjustments and, in many cases, **that companies end up closing**.

This is the result of a series of disadvantages for SMEs compared with multinationals for the following reasons:

- a. They do not have the economic capacity of the multinational to meet the costs arising from the review of substances.
- b. In the event of trying to defend them (assuming they could) and not meeting the inclusion criteria, this generates an extremely serious economic deficit for them, which would be very difficult to overcome.
- c. Faced with the impossibility of defending them they lose their registrations and, therefore, the possibility of marketing the products they manufacture.
- d. In the event that the multinationals defend and meet the inclusion criteria of the existing active substances, they do not provide access to the data required by the SMEs to maintain their registers, even against a reasonable and proportionate economic compensation for the data.

### III. - MODIFICATION OF THE DIRECTIVE: A NEED FOR A FAIR DATA SHARING

#### III.1. Problems with the Proposal of the Regulation

Although there are various points in the draft proposal of the Regulation, which could be mentioned by UEAPME, we concentrate on the most relevant points which directly affect the future of SMEs, and which if not amended in the proposal will result in the elimination of the SME in the plant protection sector.

In general, the most important points are:

1. The Regulation proposal does not distinguish between an “Existing Active Substance” or “Generic” and a “New Active Substance”, nor does it distinguish between an “Existing Plant Protection Product” and a “New Plant Protection Product”. For this reason, a period of data protection of 10 years (Articles 30 and 33) is granted independently of the type of product, without any possibility of access to the data through an arbitration system in the event that an agreement is not reached between the affected parties as arbitration being expressly excluded during the first 10 years (Art. 30.3. and 33.3.) after the inclusion of an active substance or of a plant protection product in Annex I.
2. Even worse, some “**Transitional Measures**” are introduced (**Art. 41**) which expressly exclude the existing active substances (marketed before 26th July 1993) from the scope of the measures envisaged in articles 30-40 (that means, without the possibility of access to data, or arbitration) for 10 years after the first inclusion in Annex I. It is worth highlighting that in the current draft and by application of Art. 30.3 and Art. 33.3 this 10-year period of data protection without possibility of access to data is granted through an arbitrated procedure in the event that an agreement is not reached between the notifiers (large companies) and the SMEs until a second evaluation of the substance is carried out.
3. In the case of existing active substances (same or identical to others) already included in Annex I a producer of these substances, as long as he has demonstrated the equivalence of the active substances in accordance with the procedure envisaged in Article 23, cannot include his active substance in Annex I as Article 29 on “**Data Requirements**” expressly establishes that Article 29 will be applied without prejudice to Articles 30-35, in other words, once again it falls upon granting a 10-year period of data protection without possibility of access to the data through an arbitrated procedure in the event that an agreement is not reached between the notifiers (large companies) and the SMEs.
4. Regarding the arbitration criteria established in article 38.1. 3rd point, a very subjective criterion is established for calculating the compensation which is defined as “a compensation for the risk of defending the inclusion of a substance in Annex I” without defining how this risk of defence of the substance can be evaluated. This can give rise to confusion, misinterpretation or incorrect application of the criterion. Compensation must be based on objective criteria.
5. Equally in Article 38, in the 5th point referring to the costs of arbitration it should be explicitly stated that the cost incurred from the arbitration procedure must be shared equally between the first notifier or owner of the data and the following applicants. The fact that the later applicants have to use the arbitration procedure as a means for accessing the data is due to the fact that the first notifier or owner of the data refuses to carry out an amicable negotiation or because the first notifier considers that the arbitration procedure is more expensive than the data to be compensated as may occur in the event of reviews or renewals of inclusions of active substances or the plant protection products. In these **cases** the arbitration procedure costs should be shared between the parties involved in order to avoid the unnecessary use of the arbitration procedure **as a tool to block data sharing**.

6. In Article 38 a fundamental criterion for SMEs must be introduced: “The market share of the company that pays the compensation”, which is objective and easily calculable. This is based on the fact that a national company which only intends to sale in a determined country or in a specific Zone Strip (such as “Zone C” or “the South of Europe” defined in Annex X of the Regulations proposal) should compensate depending on the real share of the market in which they will sell their plant protection products, calculated from the average volume of sales reached by these products during the last 5 years and not for an entire European market where it has not intention of selling its products.
7. Another point to introduce in Article 38, also of great importance refers to the effective time of data protection. This is important if we bear in mind that the value of the compensation that must be paid for a study will not be the same if the effective time of protection of the study is 7 years or 6 months. The basic criteria to be applied is “the longer the period of protection of the study is, the higher compensation should be paid” all of this starting from the date of presentation of the application for inclusion of an active substance of the application for the authorization of a plant protection product.
8. Regarding “Access to information and confidentiality” envisaged in Article 42, although points 1.2 and 3 seem correct, they do not cover the fact that by paying compensation, by paying for access to the data, the party paying becomes a co-owner of the data paid for. In other words, rent for the use of data without ownership should not be paid for, as to the contrary the compensation is paid for the right to own them.

### **III.2. Harmful consequences for the Mediterranean agricultural sector of the problems arising from the application of the system proposed by the Proposal of the Regulation**

The consequences of the factual situation described will be serious for agriculture (in particular in the Mediterranean Area), for Plant Health, for farmers and, above all, **for the relevant SMEs**.

Now, in the terms set out below, we will refer to the irreparable damages that this new norm will cause for the SMEs, if is maintained his current wording.

The main problem facing SMEs within the review programme of existing active substances is the high cost of investment which must be incurred to defence 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 also influence the difficulty for SMEs 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 remain competitive in the market due to the variety of products in their catalogue more than to the volume of sales of a specific product.

4. There is a clear trend in the European Commission in eliminating existing active substances from the market, invoking food safety and environmental aspects, with the consequent economic loss. This would imply for the SMEs the realisation of the studies necessary for the defence of an active substance, which may not be included in Annex I of the Directive and at the end 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 an access card, the review process tends to reduce the authorized uses of the plant protection products. This can be seen for example by the application of the different Community Directives on the maximum limits of plant protection residues in vegetable and products of vegetable origin and in the more demanding environmental restrictions.

UEAPME intends to alert that not only the SMEs will be unable to defend a large number of active substances, but it is also possible that large multinational companies are unable to defend all the active substances they wish, due to the high economic cost it represents.

Therefore, it is important to highlight that the active substance defended by the SMEs 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. This is a situation which seriously affect the national SMEs in the sector.

Some of these situations are already occurring now. A clear example is Imazalil, an active substance included in Annex I of the Directive. Some SMEs have difficulties with technical or **plant protection** products containing this substance already registered in Spain, to access the protected data to continue with its marketing.

Generally extremely large difficulties in obtaining the **letter of access** to the active substances has also been observed, as to date there is no legal obligation to share them.

Another more recent example is occurring with the active substance Fosmet. With the exclusive sale of the rights of distribution by General Química, S.A. to the company GOWAN (Margarita Internacional), the latter, despite not having the active substance included in Annex I of the Directive, does not wish to supply the technical product to the national SMEs who hold **plant protection** product registrations and, proposes to only distribute the **plant protection** product. The SME moves on, therefore, from being a manufacturer to being simple distributor.

Under these circumstances a large quantity of active substances and **plant protection** products will stay in the hands of a few multinational companies that (i) do not allow access to the necessary information for the preparation of them by other companies that formulate generic products or which (ii) carry out the supply applying an extortionate price, as it has already begun to occur. This will be related to and aggravated by an indiscriminate increase in the prices for the consumer, as there will be no real competition on the market. This practice, occurring generally, will imply the closure of formulation plants of SMEs.

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, as it is well known, at no time have the SME members of UEAPME tried to obtain free access to the protected data, but they demand fair access paying an **equitable and proportionate price**.

However, if the current draft of the Proposal is not amended as indicated below the SMEs will be irredeemably condemned to disappear from the market.

## IV. MEASURES PROPOSED BY GENERIC SMEs IN THE PROPOSAL OF THE DRAFT REGULATION. AMENDMENTS TO THE ARTICLES.

The measures proposed by the **generic** plant protection industries can be summarised in two parts: (i) compulsory data sharing of protected data; and (ii) **payment** in exchange of a fair, reasonable and proportionate economic compensation. In the event that it is not possible to reach an agreement, the dispute could be resolved by imposing arbitration on both parties.

In this sense, the Proposal of the Regulation proposes in articles 37 to 39 a system in line with UEAPME's proposal, but, and here is the crux of the question, it **inexplicably excludes its application to "existing active substances"**, as results from articles 30.1, 33.3 and 41. Moreover, the period of protection is extended to 10 years, instead of the 5 years envisaged in the current article 13 of Directive 91/414/EEC.

For all these reasons, UEAPME and the SMEs of the plant protection sector believe that the introduction of a series of amendments to the articles of the Proposal of the Draft Regulation be essential. **The most important regarding the application of the compulsory negotiation and arbitration system** when the inclusion in the Community List of an "existing active substance" occurs.

We have structured the proposed amendments in three annexes, ordered according to the importance that the modifications proposed in each have on our sector, although all of them merit consideration and would no doubt result in benefits for the SMES of the sector.

### ANNEX I: AMENDMENTS TO ARTICLES 3, 30, 33 and 41

#### 1. ADDITION to article 3. Definitions

##### (i) Proposed wording:

- “a. Existing Active Substances: *Those Active Substances that were already on the market before 26<sup>th</sup> July 1993 or substances for which the data protection period granted on their first inclusion has expired.*
- b. New Active Substances: *Those Active Substances that were not yet on the market on 26<sup>th</sup> July 1993. These substances will be considered Existing Active Substances when the data protection period granted on their first inclusion has expired.*
- c. Existing Plant Protection Products: *Those Plant Protection Products that were already marketed before 26<sup>th</sup> July 1993 or products for which the data protection period granted on their first inclusion has expired.*
- d. New Plant Protection Products: *Those Plant Protection Products that were not yet on the market on 26<sup>th</sup> July 1993 or products with a valid patent. These products will be considered Existing Plant Protection Products when the data protection period granted on their first inclusion has expired”.*

##### (ii) Reasoning:

As we explained in details in the Report, a large part of the commercial activity of the **generic** plant protection sector is based on existing active substances on the market on 26th July 1993, that is to say, two years after the date of entering into force of Directive 91/414/EC.

There is absolutely no reason to justify that once they have been included in Annex I of the Directive they cannot benefit from the regime of compulsory negotiation and arbitration that the Directive correctly introduces in the event of review of substances and **plant protection** products.

For this reason, the introduction of this distinction in the article that establishes the definitions of diverse concepts of the sector that appear throughout the text of the Proposal is of great importance.

## 2. **ADDITION to article 30.3. Data protection at first inclusion of the active substance**

### (i) Proposed wording

*“3. The arbitration procedure foreseen in Article 38 shall not apply to the information, tests and study reports referred to in paragraph 1 for the new active substances defined in Article 3, until the expiry of the period of data protection granted on their first inclusion.”*

### (ii) Reasoning

Certainly, we understand that the non application of arbitration of article 38 to the "new active substances" –that is, those that were not on the market on 26<sup>th</sup> July 2003- and, therefore, the fact of allowing their holders to benefit from a regime of exclusivity for 10 years without the possibility of negotiation by a third party regarding the confidential data that allows their registration, make some sense. These are substances on which study has been recently carried out and that have been registered by the large multinationals, and which do not enjoy tradition in the plant protection sector, as they are recently implemented products and these large companies in the sector have taken on their manufacture and marketing.

However, this reasoning completely fails if we refer to the "existing active substances" which, as we have repeatedly mentioned throughout the Report, are the fundamental basis on which the business activity of the SMEs in the plant protection sector has been developed for more than 15 years.

Impeding SMEs access –always through negotiation and economic compensation- to the essential data for the maintenance of the authorizations regarding these "existing active substances" and the **plant protection** products that contain them would have extremely serious consequences for business and, as a result, for their subsistence.

Obviously, this would have repercussions in the agriculture of our country, on generating phytotherapeutic vacuums arising from the withdrawal of essential plant protection substances and products for combating the plagues inherent in the most important crops in our country.

3. **ADDITION to article 33.3. Data protection at first authorization of the plant protection product**

(i) Proposed wording

*“3. The arbitration procedure foreseen in Article 38 shall not apply to the information, tests and study reports referred to in paragraph 1 for the new active substances defined in Article 3, until the expiry of the period of data protection granted on their first inclusion in the Member State of reference”.*

(ii) Reasoning

Certainly, we understand that the non application of arbitration of article 38 to the "new active substances" –that is, those that were not on the market on 26<sup>th</sup> July 2003- and, therefore, the fact of allowing their holders to benefit from a regime of exclusivity for 10 years without the possibility of negotiation by a third party regarding the confidential data that allows their registration, make some sense. These are substances on which study has been recently carried out and that have been registered by the large multinationals, and which do not enjoy tradition in the plant protection sector, as they are recently implemented products and these large companies in the sector have taken on their manufacture and marketing.

However, this reasoning completely fails if we refer to the "existing active substances" which, as we have repeatedly mentioned throughout the Report, are the fundamental basis on which the business activity of the SMEs in the plant protection sector has been developed for more than 15 years.

Impeding SMEs access –always through negotiation and economic compensation- to the essential data for the maintenance of the authorizations regarding these "existing active substances" and the **plant protection** products that contain them would have extremely serious consequences for business and, as a result, for their subsistence.

Obviously, this would have repercussions in the agriculture of our country, on generating phytotherapeutic vacuums arising from the withdrawal of essential plant protection substances and products for combating the plagues inherent in the most important crops in our country.

4. **REMOVAL of article 41. Transitional measures**

This article foresees the application of a transitional regime for "existing active substances" which consists of submittance to the old regime envisaged in article 13 of Directive 91/414/EEC until they are included in Annex I of the Community List, which does not foresee compulsory negotiation and later arbitration.

UEAPME believes that this provision, far from solving the defencelessness in which SMEs find themselves when they try to maintain the validity of their registers, actually prolongs and aggravates the worrying situation, in which the **generic** plant protection sector are since the Directive came into force.

And it is evidently necessary that our companies need to access the confidential data that supports the registration of the "existing active substances", through the compulsory negotiation and arbitration system implemented by the Proposal of the **Regulation**.

For this reason the transitional regime that prevents existing active substances access to the new “data sharing” regime must be removed in its entirety. If not, the consequences for agriculture and the plant protection sector will be harmful, as we have already described in this Report.

## **ANNEX II: AMENDMENTS TO ARTICLES 37 AND 38**

### **1. ADDITION to article 37 (New point 7). Data sharing**

(i) Proposed wording:

*"7. The information, tests and study reports on 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) Reasoning:

The original text of this article does not recognize specifically the fact that by paying compensation, by paying for access to the data, the party paying becomes a co-owner of all the data paid for.

In other words, rent for the use of data without ownership should not be paid for, as to the contrary the compensation is paid for the right to own them.

### **2. ADDITION to article 38.1 (Criteria 3). Arbitration**

(i) Proposed wording:

*“- 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**”*

(ii) Reasoning:

One of the elements established for setting a fair, logical and proportionate compensation consists of bearing in mind the risk of defending the inclusion of a substance in Annex I.

Although this is a subjective criterion which is difficult to determine in practice, we propose that it should be made as objective as possible, believing that the establishment of a reasonable percentage, such as that proposed, would meet this purpose, reducing, to the benefit of all parties and the margin of discretion of the arbitration organisation.

3. **ADDITION to article 38.1 (Criteria 5). Arbitration**

(i) Proposed wording:

“- the costs of the arbitration process, *which will be divided equally between the data holder and the applicant in each case*”.

(ii) Reasoning:

It seems reasonable that the costs arising from the arbitration procedure be met equally between the participating parties, as, in short, this procedure is the result of the parties inability to reach an agreement when determining fair compensation for data sharing.

4. **ADDITION to article 38.1 (New criteria). Arbitration**

(i) Proposed wording:

“- *The value of the National or Zone 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) Reasoning:

We understand that the setting of the compensation for the holder of protected data should bear in mind the share of the market of the applicants, as it does not seem acceptable that two potential applicants should pay the same amount when, for example, one of them markets the products in one country only and the other, however, distributes the products to different countries in the European Community.

With regard to the second criterion, it is based on the need that the amount finally paid refers to the moment in which the corresponding studies and tests have already been carried out, and that, therefore, the period of confidentiality that remains for a substance or **plant protection** product be considered in each case.

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

## ANNEX III. OTHER MODIFICATIONS

There are **other points** within the Regulations proposal **that affect SMEs**, to a lesser degree than the aforementioned points, but which are equally prejudicial and which are:

1. Article 9 established a **“Comparative assessment of plant protection products”** or **“principle of substitution”**, and although it outlines some considerations for its application (diversity of products to avoid resistances or acquiring experience in the use of a product), its clear aim is the removal of fundamentally “existing” active substances and **plant protection products** already included in Annex I on comparing these substances or products with others that present “a significantly different level of risk”.

In other words, to the extent that new active substances, which may present a lower level of risk are included, the existing ones will be removed from the market and with them the **plant protection products** that contain it. This is so because, amongst other reasons, there is a lot of information available on the benefits and inconveniences of existing substances, but not so much on the new substances. As they have been used very little in the field their inconveniences in practice are not known. They have only been tested fundamentally under laboratory conditions without knowing their real effects in the long term and under relatively intense use.

This evaluation also implies that despite the strong criteria and tests that the existing active substances and **plant protection products** have to pass for their inclusion in Annex I, they may be eliminated from the market after their inclusion in Annex I and after having invested important amounts of money in their defence.

Nor is it established in article 3 in “Definitions” what is meant by “a significantly different level of risk”.

### **ARTICLE 9. PROPOSAL OF ELIMINATION OR MODIFICATION**

Our proposal is the elimination of the **“Comparative evaluation of the plant protection products”** or, failing that, at least clearly define what is meant by “a significantly different level of risk” and that the new substances that are going to be marketed also be subjected to this evaluation.

2. The Regulations proposal establish that many of the procedures to be followed will be carried out following the procedure described in Article 54, particularly, the procedures established in Article 54 (2) and 54 (3). However, Article 54 deals with the “Sanctions” which the Member States may impose.

Thus, to date we do not know what the procedures to which the proposal of the European Commission refers will be. It is important that the procedures be known and the affected parties can make observation before the European Commission adopts the Regulations.

3. Article 5. **“Requirements for granting authorizations”** as well as Articles 24. **“Decisions on safeners, synergists, adjuvants and co-formulants”** and Article 25. **“Derogation for safeners and synergists”**, refer to the need to present a complete dossier of information for the inclusion of the safeners and synergists in Annex I.

Specifically in Annex IE, however, the period of data protection is not established for them in **Articles 30-35**, nor **Articles 36-38** refer to the system to be followed for sharing data, nor to the arbitration to which they may be subject. We consider that these products should be cited in Articles 30-38.

Our proposal is that in Article 37 “Interchange of data” a new Point 8 be included, which indicates the following:

**ARTICLE 37. PROPOSAL FOR THE ADDITION OF A POINT 8.**

***“8. The procedure established in this article will also be applicable to the safeners and synergists at the time of their inclusion in Annex IE.”***

Brussels, 5<sup>th</sup> April 2006

 The logo for UEAPME features the acronym 'UEAPME' in a bold, blue, sans-serif font. To the right of the text is a blue square containing a white silhouette of a map of Europe with five white stars arranged in an arc above it, similar to the European Union flag.	<p>UEAPME is the employer's organisation representing the interests of crafts, trades and SMEs from the EU and accession countries at European level.</p> <p>UEAPME has 78 member organisations, which represent crafts and SMEs across the whole of Europe, covering over 11 million enterprises with nearly 50 million employees.</p> <p>UEAPME is a European Social Partner.</p>
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