Association of Users and Distributors of AgroChemicals in Europe

Daniel Roques
Président
✉ *Adresse pour courrier en retour*
Boite postale 27
41 600 Nouan-Le-Fuzelier
✆ *téléphone:* +33 (02) 54 96 88 13
télécopie: +33 (02) 54 88 41 84

Stéphane Delautre-Drouillon
Secretary-General
✉ *Address for return mail:*
rue de Pont, 33
B-7500 Tournai
✆ *telephone:* +32 (69) 89 14 18
facsimile: +32 (69) 67 17 25

31st August 2006

AUDACE's comments and observations

on the proposals for

Regulation [2006/0136 (COD) - COM (2006) 388 final]

and

Directive [2006/0132 (COD) - COM (2006) 373 final]

relating to the marketing and

sustainable use of Plant Protection Products (PPP)

Texts presented to the European Parliament and Council on July 12th, 2006

CONTENTS

[1] Convention on the Contract for the International Carriage of Goods by Road (CMR) (Geneva, 19 May 1956)

INTRODUCTION

The Commission presented the two proposals, for a regulation and a directive to the European Parliament and Council on July 12th, 2006.

They are the outcome of the work in the last five years on the regulations involved in revising Directive 91/414/EC and, on the Directive, the thematic strategy on the sustainable use of PPPs on which AUDACE was one of the parties involved the Commission consulted.

Once implemented, these rules, which are more constraining on Member States in terms of marketing MA, will replace Directive 91/414/CE.

As for the proposed directive, the aim here is to lay down uniform requirements and aims to be achieved in using PPPs by all Member States, while allowing them the option to revert to self-regulation.

As the two texts refer constantly to one another, it seems appropriate to consider them together.

We will start by listing the measures which AUDACE proposed but which were ultimately not adopted (I), comment on the measures which were adopted, wholly or in part (II) and look at the measures adopted which were not included in our proposals (III).

I- Measures not adopted:

1. The proposals concerned here are as follows:

   - Regulations accessible to individual professional and non-professional users
   - MA centralised at Community level
   - Labelling full contents of PPPs
   - Clear recognition of adverse effects over and above toxicity symbols
   - Industry adopting state of the art science and technology
   - Stop making and marketing products which do not definitely comply with essential requirements in third countries
   - Applying the rules to 'green marketing'
   - Effective control, even prohibition, of advertising in favour of objective communications platforms
   - Packaging products for rational use
   - Modifying practices tending to anticipate selling products 'out of season'
   - Modifying price strategies and sales incentives for maximum use

II- Measures adopted, wholly or in part

A- Data protection

2. Removing protection for data generated in the course of reviewing old active substances is undoubtedly a major success with a view to re-establishing competition from generic products in the financial interests of users and innovation.
   This success is only partial, however.

3. In providing for the possibility of protecting data in connection with renewing MA for commercial specialities, the Commission is still leaving the door open to all possible kinds of abuse.

4. Admittedly, this protection is linked to renewal applications involving new formulations and/or new uses for PPPs.

5. As no limit has been set on these conditions, however, all that an applicant has to do is to change just one minor factor in their product formulation for protection to arise out of the ashes of Article 13 of Directive 91/414/EC.

6. As we see it, and along the line of the arguments we have put forward during each consultation on revising the Directive, protecting data is only legitimate, objective and proportionate if the time involved does not exceed that which a patent gives on an innovation.

7. This is why we have never been against protecting data on new active substances, on the grounds that ten years' protection is still less in theory than the protection which lodging a patent on such substances confers, or of the CCPP if one is obtained.

8. In fact, and since the Commission ultimately conceded our initial objections to Article 13 of Directive 91/414/EC, protecting data involved in renewing the marketing authorisation

(MA) for a PPP containing an old substance must be made subject to the patentable nature of the modification alleged and that it does actually bring advantages in terms of benefits and risks.

9. It is also regrettable that reforming Article 13 of Directive 91/414/EC will not be done until all old active substances have been reviewed.
So, while considering it proper that protection must be limited to enable competition to take place, and must only relate to the research actually required for the purposes of regulation, such that applicants are not given a protection period which is abnormally long by presenting pointless new studies, the regulation as proposed has no effect on such abuses in the past or in the future, which are definitely the result of breaches of competition rules.

10. In effect, the sophism whereby protection in excess of that granted by a patent is somehow favourable to innovation is still too deeply rooted, whereas all that has to be noted is that the industry, which is considered innovative, spends far too much time prolonging the protection of those old discoveries not covered by patents to making new ones out of them.
As for the improvement hoped for in terms of protecting public health and the environment, such sophism is undoubtedly contrary to the aims pursued.

B- Sharing test and study data involving use of vertebrate animals

11. This is another remarkable advance; but it is still held back, unfortunately, by the absence of enforcement measures to ensure that it is actually applied.
By contenting itself with stating that players must do everything to ensure that these tests and studies are shared, and that potential applicants are only bound to share in the costs of the information they have to submit to meet authorisation requirements, the Commission is still leaving the door open to abuses by those holding the MA concerned.

12. By referring cases where agreement cannot be reached to the courts, the draft provisions limit themselves to copying the situation prevailing in the USA, which augurs more likely in favour of negative effects against potential MA applicants in Europe than the legal systems of the Member States are not deemed to impose, and work along the lines of their US counterparts which are more accustomed to act in the context of rules which do not provide for complete certainty in law.

13. We can therefore only repeat our suggestions on monitoring the costs of such tests and studies by an independent, impartial authority and assigning them in proportion to operators' actual market shares.

C- Negative list of co-formulants

14. This measure is in line with our proposals on setting essential requirements for co-formulants as well.

D- Comparative assessment and substitution

15. Whatever effects this measure may have on availability of products to users, we believe it is necessary to meet essential requirements, given that it also applies just as much to

replacing an old substance with a new one as to not registering a new substance after comparing it with an old one.

16. The Commission has also been careful to make the substitution subject to the absence of appearance of resistances to substances which remain authorised in target organisms.

17. This measure is in line with our proposal for Community registration of substances (or, to be more precise, of products) independently of the industrial logic of producers.

E- Packaging, labelling and advertising

18- The requirements here are manifestly insufficient, especially in terms of advertising.
If it is not to be prohibited, we propose that advertising for PPPs be replaced by objective communications platforms, or, at least, that it should be regulated and inspected along the lines of drug advertising.

F- Keeping records, organising controls and sanctions

19. These provisions, which cover the whole chain from the manufacturer or MA holder to the user, are in line with our views, given that risk management must start with knowing how much of each PPP has been put on the market, where it is used and whether it complies with the terms of supply under its MA, in terms of both production and use.

G- Minor uses

20. The draft regulations go beyond our hopes on the increasingly critical question of extending MA to minor uses.
First, in defining 'minor use' as using a PPP on a crop which is not very large, or on a crop which is very large if this is in response to exceptional needs.
Then, in granting professional users, or their agricultural organisations, the right to apply to national evaluation authorities.
And, finally, laying down in law that refusal on the part of the registration holder cannot be final.

H- Public access to information

21. While there has been a real advance in terms of the obligation to justify all refusals to access information in objective terms, it is still highly regrettable that the full composition details of PPPs remain confidential.

22. Indicating the active substance alone does not enable the user – who, otherwise, paradoxically, are provided with training which is extremely complete, to say the least – to choose between PPPs containing co-formulants of different toxicities, without products being based on different classification on this point either.

I- Emergencies

23. Subject to the reservation that the existence of such a situation may in particular be raised by users in the light of their observations, incidents and unwanted effects when using, the measures here are in line with our suggestions.

J- Approval of similar PPPs

24. We believe very positive introducing in the regulation the idea of the similarity of a PPP produced by a manufacturer other than the one which initially applied for the assessment if its composition is not substantively different from that shown in the deed approving the substance.

K- National Action Plans (NAPs) and limiting/restrictive measures

25. Combining these two types of testing in the same point of our observations is justified on the grounds that many Member States have already included limiting and/or restrictive measures the Commission is proposing in national action plans.

26. As well as the obligation to adopt NAPs, these measures include:

- Training professional users
- Informing the general public
- Applying Directive 98/34/EEC on minimum requirements applicable specific to a member State, i.e. the obligation to notify these requirements
- Inspecting sprayers
- Prohibiting airborne sprays except for exemptions for justified applications and PPPs expressly authorised for that purpose
- Setting up barrier strips, hedges and banning PPPs in some areas, such as NATURA 2000, public gardens, etc.
- Collection and recovery scheme for PPP packaging waste and obsolete chemicals
- Specific MA for PPPs intended for non-professional use
- Provisions governing PPP tank-mixes, their dilution levels and cleaning sprayers
- Using alternative methods and Integrated Pest Management
- Certifying distributors and advisers, professional users remaining optional

27. Where users are concerned, many of these measures have already been applied under grant conditions implemented under the new CAP.

28. Otherwise, it is disappointing to say the least to farmers, who are more restricted than any other occupation that the draft directive allows such room to sprayer inspections, going as far as giving them an entire annexe of their own which seems to reinvent the inspection process which farmers today, and even more tomorrow, already carry out quite naturally of their own accord each time they use them, if only for financial reasons or purely common sense.
It is high time, and our supra-national authorities should lead the way here, that people stop seeing farmers as limited and unthinking.

By way of comparison, the conditions in which PPPs are made are just as prone to the risks involved in ussing them, without any specific provisions being proposed beyond general rules for the chemicals industry.

29. This being the case, and given that inspecting sprayers, like all the other measures above (some of which are in line with what we proposed) is part of a politically and socially correct consensus, the only point in making these remarks is that to remind people that regulations are more likely to achieve their overall aim of being complied with by most people if the people they are directed at can understand them and accept them both morally and intellectually.

III- Measures not included in our proposals

A- Not registering substances based on CMR[2] hazard criteria and endocrine disruptor status

30. No-one would deny nowadays that protecting public health and the environment takes precedence over protecting plant health … at least insofar as the former is not put at risk by food shortages as a result of neglecting the latter.

31. It would therefore be advisable to modulate the measure involved here, especially by taking account of the circumstances which bring risks about. But, given the consensus which has already come about (point 29), any proposals to moderate or provide exemptions are very unlikely to succeed, given the opulence the European Union has enjoyed so long.

B- Low-risk substances and products

32. We approve the exemption for cases of shorter period for considering applications for low risk PPPs.

C- Informing neighbours before spraying

33. This requirement could be linked to MA for requirements for marketing and using PPPs.

34. While apparently socially correct, for users to implement them would seem difficult in practice, even unrealistic, and leaving them out would be liable to turn the countryside into legal disputes for ever.

35. As this requirement only applies, very fortunately, to such PPPs as the national authorities decide, and not to all products, users might find themselves harassed or even permanently subjected to searches by their neighbours wanting to know if the labels for the PPPs they are using include the obligation in question.

36. This restriction also assumes there are systematic breaches of the provisions of the law on safe distances for protecting neighbours and against drifts when spraying.
This measure is therefore a licence to sue.

[2] Convention on the Contract for the International Carriage of Goods by Road (CMR) (Geneva, 19 May 1956)

D- Abolishing provisional MA

37. Issuing provisional MA for PPPs where new substances have not yet been evaluated at Community level and which are therefore not included in Directive 91/414/EC, annexe 1, will now be abolished.

38. We think this measure will help people understand the centralised process for evaluating active substances and even be aware that it exists.
It eliminates the distortions of competition due to the differences in how member States handle issuing provisional MA, or not, and so puts all farmers in the EU on an equal footing when it comes to the availability of the PPPs in question.

39. It also comes with provisions on strict deadlines for evaluating substances and issuing MA which can therefore be used against the authorities concerned if they are overrun.

E- Regional MA and mutual recognition

40. Our proposal for a centralised MA was rejected for the sole reason as follows (grounds for draft regulations, section 20) :
*« Plant protection products containing active substances can be **formulated in many ways and used on a variety of crops, under different agricultural, ecological and climatic conditions.***
***Authorisations for plant protection products should therefore be granted by Member States**. »*

41. On the other hand, the rules do not ignore the fact that the aim is to harmonise provisions on PPPs, and that MA any one member State grants must be accepted by other Member States where conditions are comparable (section 24 of grounds).

42. Hence the proposal to divide the EU into licensing areas to make it easier for Member States to recognise one another's MA within the same area.

43. While this solution may seem to be another step on the long road towards centralised MA, it is in fact nothing more than a magnificent formulation of the question, **why make things easy all of a sudden when you can keep them complicated ?**
We feel bound to say this, on why the idea of regional MA is still more at odds with the principles of proportionality, subsidiarity, objectivity and necessity as that of national MA as used today.

E-1- Agricultural, environmental and climate conditions differ between Member States

44. There is no denying these differences exist.
But, when it comes to justifying national or regional MA, they are irrelevant.
They have objective reality all the same within the territory of individual member States, typically, in France, which, as well as metropolitan France, also includes the French West Indies, Guyana and Réunion.

45. So, if we start allowing for their effects, both reasonably and objectively, this would be more likely to lead to the idea of micro-regional MA, or even MA for individual plots, more than it would to combine the historical borders of certain countries arbitrarily and reduce

the agricultural, environmental and climatic diversity of the EU to three zones putting Lille, Nicosia and Seville in the same basket so to speak as part of the southern area.
Which is even stranger, given that these conditions are actually more comparable between Northern France and Belgium or Luxembourg, which are, however, in different zones.

46. It is not because it would undoubtedly be unrealistic to adopt a specific MA procedure for each of the innumerable agricultural, environmental and climatic conditions which exist both within the EU itself and within each region of each member State – even sometimes within one farm – that it is justify to dwell on this other sophism whereby the idea of national MA was adopted in 1991.

E-2- Different formulations, different crops

47. As the active substances and co-formulants contained in PPPs are subject to centralised, harmonised evaluation before there can be any possibility of a MA for all Member States, the only possible reason this leaves for regional MA is if they are combined and formulated as different mixtures.

48. Whether this hypothesis is relevant, depends on how the same PPP or, to be more precise, two similar PPPs are formulated by two separate manufacturers, or whether the same manufacturer is obliged, or wishes, to produce different formulations.

49. In the first case, each manufacturer obviously has its own MA, so that the question does not arise.
So the same formulation relating to each « *zonal* » MA can be derived from a centralised marketing authorisation without there being any problems for the reason stated.

50. In the second case, the Commission would find it hard to nominate just one PPP made by the same manufacturer holding a MA in a member State which could not be used in other member States because it was objectively necessarily formulated differently in terms of the conditions above (sections 44 to 46).
We can confirm that no such PPP exists, and that confirmation has never been denied by any competent authority consulted or any manufacturer.

51. Using different formulations means increasing production costs by using different production processes.
Which means that a manufacturer would have to have a very good reason for doing so.

52. It could in fact be compelled to do so by specific national provisions prohibiting it from using the formulation accepted in other member States on the grounds of increased local protection for public and environmental health.
Such differences of opinion between competent national authorities are becoming increasingly rarer nowadays, and the Directive is aimed precisely at abolishing them completely, stating that, *« … the objectives of this Directive, namely to protect human health and the environment from the possible risks associated with the use of pesticides, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, … »*

53. Manufacturers can also decide to use different formulations in different member States of their own accord.

The only aim here is to exploit artificial partitioning of the single European market by using national MA as marketing tool against parallel imports.

54. This practice is all the more unacceptable given that, generally speaking and very luckily very minor and irrelevant as they are, differences in formulation may have an increased impact on PPP toxicity.
Which is why the Commission itself came down so hard on a similar case in its decision in the ZERA/MONTEDISON case (93/554 EEC) of June 22nd, 1993.

55. It follows from this that, whether they are compelled to do so or do so of their own accord, individual manufacturers can never be justified in using different formulations to take account of differences in agricultural, environmental or climatic conditions, however specific they may be.

56. As for using the same PPP on different crops, the relationship which exists between the need for national or « *zonal* » MA and the uses authorised under that authorisation is stretching a point to say the least.

57. Crops are grown from seeds which themselves have been evaluated centrally at Community level, and which appear in the European seed catalogue.
Obviously, some of them are not suited to the conditions, mainly climatic ones, in all member States. If the crops concerned are not found in some countries, this means *ipso facto* that the PPPs specific to them will not be used.
So centralising MA for these PPPs would have no more effect than centralising seed registration.

58. Where a crop is not common to all member States, the idea of a centralised MA would not in any case have any more effect than the regional MA as proposed. The range of crops found in France is indisputably incomparable to those found in Cyprus or Malta.

59. Where crops are common, all that is required, if necessary, is to adjust the dose rates to suit specific conditions, along the lines (at least, we hope) of the idea of « *zonal* » MA.
By way of comparison, for lack of any sector analogy, we can only stress that it is not because road speed limits differ because of the state of the road network or specific national legislation that cars are not the same throughout the EU.

60. And, finally, if centralised MA proved to have some risks to a member State, and we cannot imagine why such risks would be excluded from the areas as defined in the draft regulation, such exceptions would be minimum specific requirements notifiable under Directive 98/34/EC, as emphasised by ground 8 to the draft Directive.

E-3- Conclusions

61. Centralised MA are perfectly in line with the principles of subsidiarity and proportionality.

62. They are widely used in all major non-member states, such as the USA, where agricultural, environmental and climate conditions vary at least as much as they do within the EU.

63. The proposed « *zonal* » MA and mutual recognition requirements have set the limits on national sovereignty here.

64. Farmers still cannot understand why PPPs are not harmonised completely, while everything else they produce can circulate freely within the EU.

65. While they seem more liberal « *zonal* » MA can only increase that incomprehension.

66. Centralised MA offer major savings to manufacturers, member States and the EU itself.

* *

*

We would be grateful if you would bear in mind these observations and comments in the course of the Parliamentary committee's work responsible for examining the two items of Community legislation involved.

Daniel ROQUES
Chairman, AUDACE