



UNION EUROPEENNE DE L'ARTISANAT ET DES PETITES ET MOYENNES ENTREPRISES
EUROPÄISCHE UNION DES HANDWERKS UND DER KLEIN- UND MITTELBETRIEBE
EUROPEAN ASSOCIATION OF CRAFT, SMALL AND MEDIUM-SIZED ENTERPRISES
UNIONE EUROPEA DELL' ARTIGIANATO E DELLE PICCOLE E MEDIE IMPRESE

Considerations on the Report of MEP Breyer

On the Proposal For A Regulation Of The European Parliament And Of The Council Concerning The Placing Of Plant Protection Products On The Market

UEAPME, as the European Association of craft, Small and Medium-Sized Enterprises, welcomes the publication of the Report of MEP Breyer on the above mentioned proposal for a Regulation on the placing of Plant protection products on the market. In fact the Report contributes, under certain aspects, to improving the management of the authorization system for placing plant protection products on the market.

Nevertheless UEAPME wishes to raise some important questions, with the aim to point out the needs of European SMEs.

With this purpose we wish to remind that SMEs are in fact the driving force of EU economy as they represent about the 99% of the companies, produce the 60% of the added value and employ about 75 millions of workers. In the plant protection product sector there are no substantial differences in these percentages.

UEAPME considers that the proposed Regulation, even if improved in the actual version by MEP Breyer, may continue to alter the competition in the plant protection product sector, favouring the creation of monopolies or consolidating those already existing. This defies reason: at the same time the European Union founds its principles on free circulation of people and goods, it proposes a Regulation containing provisions which may create infringements to free competition.

In particular UEAPME welcomes as positive the following principles proposed in the MEP Breyer's Report:

- **Data sharing:** avoidance of test repetition is supported. We consider this avoidance **should be compulsorily extended to ALL data for existing substances**, not only those on vertebrates, needed for supporting the authorization of a plant protection product, **under fair and proportionate compensation to be paid to the data owner**. Rules for data sharing have to be indicated in the same Regulation for uniformity throughout EU. Test duplication is in fact totally uneconomic, since against a big increase of costs for industry and of workload for competent Authorities there is no real advantage demonstrated for safety. Moreover it has to be taken into consideration that data protection has been used in the past as a tool to influence the competition and the risk it may happen in the future is very high (Amendments 8, 17, 18, 19, 20, 34, 43, 49, 50, 51, 58, 82, 113).
- **Data protection limit:** It is crucial that time for **data protection after first authorization to place a plant protection product on the market remain fixed at 10 years**. We highly appreciate that MEP Breyer did not amend such point.
- **Parallel import:** UEAPME shares the idea to introducing in the text of Regulation clear provisions for parallel import. The lack of rules may only generate confusion and favour the development of irregular uses.

- **Evaluation of substance**: We wish to express our favourable opinion for the principle that a substance should be evaluated for all proposed uses and not only for one representative use. This would in fact avoid the duplication of the same kind of evaluation at Member State level and the unavoidable repetition of studies (Amendment 42).
- **Substitution principle**: It is agreed the deletion of art. 48 paragraph 2, beside the deletion of the full art. 48 would be preferred.

UEAPME remains however highly concerned about the following points proposed in the Draft Regulation:

- We cannot see the needs to foresee several renewals, considering that competent authorities keep always the right to suspend or withdraw an authorization whenever health or environmental concerns raise; they also have the right to ask further information to holders. **Continuous renewals may be used as a tool to prolong indefinitely the data protection period** (Amendment 56).
- Introducing the authorization of co-formulates is a useless uploading of the procedures. Their placing on the EU market is already considered in the framework of REACH. **It is therefore considered as more correct a negative list addressed to avoid the presence of co-formulates with highly negative profile** (similar cut-off criteria of aa.ii.s: CMR 1-2, PBT, vPvB).
- The presence of *transitional measures*, i.e. the maintenance of data protection provisions in force in the EEC Directive 91/414, as described in art. 77, vanishes completely the attitude of deregulation of data protection after the 10 years from first authorization (**included in art. 56 and positively not amended by MEP Breyer**). As effect of EU revision of the existing active ingredients and of the actual provisions on data protection, the SMEs have already lost a large number of registrations and a substantial value of their turnover. Therefore we wish to remind the high **importance of applying the rules since from the very beginning**.