



Association Internationale de la Savonnerie, de la Détergence et des Produits d'Entretien
International Association for Soaps, Detergents and Maintenance Products



European Biocidal Products Forum



EUROPEAN ASSOCIATION OF
CHEMICAL DISTRIBUTORS

Ms Nina Cromnier
Chair of ECHA's Management Board

Cc:
Geert Dancet, Director of ECHA
Jukka Malm, Director of Regulatory Affairs ECHA

Brussels, 16 April 2013

RE: Biocidal Products Regulation – draft Implementing Regulation on fees payable to ECHA

Dear Ms Cromnier,

With this letter, A.I.S.E.¹, EBPF² and Fecc³ would like to echo the concern of the biocides standing committee that failed to reach an opinion on the draft Regulation as regards fees payable to the European Chemicals Agency (ECHA) at its last meeting in March. Considering that the proposal could be very detrimental to the competitiveness of the biocides industry in Europe, we urge ECHA, Member States' representatives and the European Commission to further consider opportunities to revise it.

We understand that the Appeal Committee will examine the draft Regulation on fees payable to ECHA on 3 May and that on 18-19 April a meeting will be organised between ECHA and some Member States in order to discuss ECHA's biocides activities.

A.I.S.E., EBPF and Fecc would like to herewith share some key recommendations on the draft proposal. They are vital to ensure that the Union authorisation for biocidal products is a success, that ECHA does function for biocides and finally that the level of the fees are not disproportionately affecting SMEs competitiveness and the availability of biocidal products that contribute to public health in Europe.

Start with lower fees and review them in 2015 on the basis of experience

A.I.S.E., EBPF and Fecc welcome the proposal that is made to review the Regulation on fees and charges payable to ECHA at the latest in 2015. **However, in view of the uncertainties in the new authorisation system, we strongly recommend to start with relatively low fees, instead of starting high, and re-examine the financial modelling of ECHA in the light of the first two years of experience.**

If these fee levels are maintained⁴, the biocides industry will not be able to use the Union authorisation process or not at the level foreseen. ECHA is likely not to function at all not because of lack of resources but rather by being unattractive to the vast majority of biocides companies in Europe, even the largest. Meanwhile, a heavy administration system including IT and human resources will have been put in place at ECHA that will not serve its purpose.

The legislators adopted the Union authorisation as one of the key element to cope with the safety objectives of the new Biocidal Products Regulation. However, with such an unattractive structure of fees, companies are most likely to abstain from using the new Union scheme which will evidently delay the accomplishment of the

¹ A.I.S.E. is the voice of the Soaps, Detergents and Maintenance Products industry in Europe. Its membership totals 37 national associations in 42 countries, covering about 900 companies ranging from small and medium-sized enterprises to large multinationals. Biocidal products manufactured by A.I.S.E. members include a vast range of disinfectants for household and institutional use, as well as household insect control products.

² The European Biocidal Products Forum (EBPF) is a sector group of Cefic, composed of more than 70 companies and trade associations representing the industry that places a wide range of biocidal products on the market for the benefit of EU citizens.

³ Fecc is the voice of the Chemical Distribution Industry in Europe. With a growing membership of companies and national associations, Fecc represents around 1,700 companies of which many are small and medium sized enterprises (SMEs). Fecc's mission is to promote the industry in order to ensure a sustainable business environment for the sector in the short, medium and long term. Fecc members are notifiers of active substance, formulator of biocidal products and distributor of (imported) biocidal commodities.

⁴ The ECHA fee covers the costs for administering the Union authorisation incl. the reimbursement of the members of the Biocidal Products Committee who act as rapporteur and co-rapporteur. In the current proposal, the ECHA fee is set at 80k€. On top of that, the applicant will have to pay the evaluation work directly to the evaluating competent authority.

objectives of the Regulation, already long overdue given the delays encountered during the 13 years since Directive 98/8/EC entered into force.

We believe that every incentive should be given to encourage industry to make maximum possible use of Union authorisation and achieve the safety objectives of the Regulation faster. Nevertheless, the process is untried and, historically, those going first have generally faced the unavoidable truth of acting as guinea pigs such that later dossiers benefit from lessons learned. It is inevitable, but when combined with such an unattractive fee structure, any incentive to go first is effectively eliminated.

Therefore, the fee charged by ECHA should be lowered, at least for the first two years to encourage use of the Union authorisation. It would be unacceptable to propose a fee for purely administrative tasks (current proposal is 80k€) that is even of the same order as the fee charged for the full evaluation for authorisation of a biocidal product (e.g. 2,5k€ and 30k€ for the most expensive MS, with full cost recovery).

Another source of income for ECHA: technical equivalence

Other sources of revenue than just authorisation dossiers must be considered in the ECHA financial modelling. According to article 54 of the Biocidal Products Regulation, ECHA is in charge of performing technical equivalence assessments. Technical equivalence is needed if an active substance is purchased from a different manufacturing source than the one covered in the active substance dossier. It ensures that the hazard data and risk assessment done on the active substance from the original source remain valid for the new source.

In the draft Regulation on fees payable to ECHA, the fees for technical equivalence range from 5.000€ (different manufacturing location but same manufacturer); 20.000€ (when only analytical data need to be reviewed to establish technical equivalence); up to 40.000€ (when more work/assessment is needed).

It is expected that requests for technical equivalence will be numerous, e.g. for the purpose of mandatory data sharing among suppliers. Technical equivalence assessments should therefore be seen as a major source of income for ECHA for the next two years. It can most certainly balance the potential "losses" that a lowered Union authorisation's fee could create.

We propose that the financial modelling of ECHA for the Union authorisation be reviewed taking into account the important source of income that could be generated by technical equivalence.

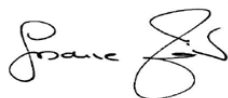
The Biocidal Products Regulation is an expensive programme for industry. At Union level, the proposed ECHA fees mean that the bureaucratic handling of a dossier is in the same order of cost as the development of the dossier by companies (including scientific data), and far in excess of the fees charged to actually evaluate the information, which should be the primary focus of the regulatory procedure. For example, for a company with exceptional annual sales for a biocidal product of 1 million euros, the return on investment would be achieved approximately after 15 years.

To limit the impact of the proposed Fees Regulation on the competitiveness of the biocides sector, including the SMEs, and to motivate Union authorisations in a way to achieving faster the safety objective of the Regulation, A.I.S.E., EBPF and Fecc strongly recommend to amend the Commission's proposal as follows:

1. start with relatively low fees and re-examine the financial modelling of ECHA in 2015 in the light of the first two years of experience;
2. consider other source of income such as the establishment of technical equivalence by ECHA.

We thank you for considering our recommendations here above.

Yours Sincerely,



Susanne Zänker
Director General of A.I.S.E.



Raf Bruyndonckx
Sector Group Manager Cefic EBPF



Uta Jensen-Korte
Director General of Fecc