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### Criteria for populating Reg 1107 Annex III on coformulants

Dear Mrs Fabrizi

We welcome the significant progress which has been made for the population of Annex III in Regulation (EC) No. 1107/2009, primarily through linking the proposed criteria with existing horizontal REACH and CLP legislations. In our view such criteria should be transparent, have clear processes, offer the opportunity for stakeholder engagement, and have predictable implementation timelines.

Therefore, we would like to raise some concerns which recently arose in connection with one of the potential criteria for populating Regulation (EC) 1107/2009, Annex III. Our understanding is that the criteria may contain a clause to “grandfather” in the national negative lists maintained by individual Member States (i.e. to incorporate substances from existing national lists without subjecting them to a common selection methodology). In our view this is unnecessary, as the vast majority of the substances currently listed on these lists are already captured by the other criteria e.g. harmonised classification for CMR 1A/B properties, SVHC listing for PBT/vPvB properties, etc.

Furthermore, such a clause could be prone to “last minute updates” by individual Member States prior to publication of the legislation, thus introducing substances which are not aligned with the other agreed criteria. This concern was triggered by the recent update of the “Spanish list” (found here:

<http://www.mscbs.gob.es/ciudadanos/saludAmbLaboral/fitosan/prodfitosan/docs/Coformul1018.pdf>), which introduced substances with classifications of less concern than those discussed to date, as well as one substance where the RAC opinion had not yet been adopted into Annex VI of CLP.

Given our desire for a transparent and consistent process allowing adequate time for reformulation of any impacted formulations, we request that the use of any “grandfather” clause be reconsidered.

On a separate topic, in connection with the “Spanish list”, we wish to draw your attention to regulatory action taking place around crystalline silica. Recently the French competent authority withdrew its proposal to ECHA for harmonised classification of respirable crystalline silica. Furthermore, the Commission introduced legislation specifying a maximum workplace Occupation Exposure Limit (OEL) of 0.1mg/m<sup>3</sup> (Directive (EU) 2017/2398), which also applies to work generated processes. In our view, this is a pragmatic approach to the control of this

ubiquitous natural substance, and further inclusion of this substance in Annex III in addition to the OEL is unwarranted.

We are looking forward to the official publication of the criteria for population of Annex III, so that we can continue to provide constructive engagement for a workable and efficient legislative framework.

Yours sincerely

A handwritten signature in black ink, appearing to read 'S. N. Rutherford', written on a light-colored background.

Stuart Rutherford  
Director Water and Food Policy

Cc  
K. Nienstedt  
K. Berend