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Cc:
M. Rubbiani – DG Sante
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ECPA letter on criteria for populating Reg 1107 Annex III on coformulants

Dear Mr Berend,

ECPA understands that the draft Commission regulation modifying Annex III of Regulation (EC) 1107/2009 (unacceptable co-formulants) was on the SCoPAFF agenda for an exchange of views and possible opinion on May 18-19th. Subsequent to this, it is understood that following the launch of a two week written-procedure consultation, the agreement process was put on hold at the request of one of the member states.

We would like to re-emphasize that the latest draft Annex III which was put forward in May would provide a stringent and challenging, but robust framework based on REACH and CLP. This proposal would support product authorization, and contribute to ensuring a continued high level of protection for both operators and the environment.

However, in advance of the next exchange of views and ahead of any future SCoPAFF vote, we would like to try to address what we understand to be the concerns of the member state that asked to stop the procedure. In this context, we wish to reiterate the following key principles for placing substances on the Annex:

- A transparent and consistent process for the identification of unacceptable co-formulants for future addition to Annex III is required. If hazard-based cut-off criteria are used for identification purposes, it is essential that only harmonized classifications are used which have been agreed by the relevant competent authority and have been adopted at the European level, i.e. via ECHA and the CLH process. This appears to be aligned with the principles flagged for the European strategy for sustainable chemicals.
- An adequate transition time for reformulation of any impacted formulations must be provided, acknowledging that using hazard-based cut-off criteria does not equate to a risk with using these co-formulants.
- For the consistent interpretation of Annex III, ECPA is supportive of setting a de minimis level for impurities in finished formulations. We wish to repeat again that these should be consistent with the cut-offs specified in the REACH and CLP legislation. In general for these hazard classes, it is therefore understood that this limit should be set at the CLP generic concentration limit (GCL) of 0.1% w/w (see REACH, Annex II, 3.2), except of course when a substance has a specific concentration limit (SCL) defined in CLP Annex VI.
- It should be noted that SCLs are sometimes set for hazard classes other than for the carcinogenicity, mutagenicity, and reprotox mentioned in the preamble to the draft Annex III, and thus not all SCLs are relevant. For example, a SCL set for skin irritation should not be relevant for a substance listed in Annex III. It should also be

noted that while the threshold for reporting Repro 1B substances in section 3 of a safety data sheet (SDS) is 0.1%, the cut-off for classification is actually 0.3% w/w.

- Apart from cases such as when a SCL has been set which is different from the GCL of 0.1% w/w , there is no scientific or legal basis for selecting a value for impurities which is lower than the GCL which is used for classification and labelling, and which is therefore reported on SDS. Deviating from these values would cause significant business disruption and cost because the entire chemical industry works to these standards.
- It is understood that Regulation (EC) 1107/2009 Article 27 prevents the intentional use of a substance listed in Annex III in a formulation as a co-formulant at any concentration. The 0.1% w/w (or SCL, etc) impurity limit therefore serves only as a practical limit for analytical and enforcement purposes.

We would like to offer our support for the finalization of Annex III and would be pleased to engage as may be needed in any further discussion on this topic. In the meantime, should you have any further questions, please do not hesitate to contact me.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'S. N. Rutherford', with a small dot at the end.

Stuart Rutherford
Director Water & Food Policy