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European Commission
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Brussels, 25 June 2009

Dear [redacted]

Dossier submission for the re-approval of the active substances glyphosate, sulfosulfuron and silthiofam currently listed on Annex I of Directive 91/414/EEC

Given the forthcoming adoption of the new Regulation to replace Directive 91/414/EEC, we are writing to you to kindly seek further clarification on the process for the re-review of active substances that have been included on Annex I of Directive 91/414/EEC.

Article 18 of the new Regulation provides the possibility for the Commission to establish a work programme to re-evaluate these active substances and we understand that discussions on the likely process are already underway in your services.

However, Article 15(1) of the Regulation requires producers to notify the Commission and Member States about applications for re-approvals at least three years before the expiry of an inclusion. Given the current uncertainty regarding the process and especially about the prevailing timelines, we would like to take this opportunity to inform you of the active substances that Monsanto Europe S.A. is planning to support through the re-review process. For proper planning purposes, we include a list of all relevant substances that are due to expire before the end of 2015.

The following provides a list of substances that we have already indicated to you that we will support and that expire in the period 2010-2012:

- **Glyphosate** (as a member of the Glyphosate Task Force)
- **Sulfosulfuron**

In addition, we are also currently planning to support the following active substances that will expire between 2012-2015:

- **Silthiofam**

For the active substance glyphosate our company is currently in negotiations with other potential notifiers as our submission for this substance will be as part of the Glyphosate Task Force. We would stress that this letter is not intended as a full application, and we will provide you in due course with the information required to ensure compliance with Article 15 of the new Regulation.

We would welcome any further information from your side in the near future to ensure legal certainty in our planning for the submissions. There are a number of issues where your early clarification would be particularly important, including:

- **Nomination of rapporteurs for the active substances in question.** This would allow further discussions as regards the details of the submission, including justification of new studies. Early notification of a rapporteur will also assist in ensuring compliance with Article 62(2), to verify if vertebrate studies have already been performed or initiated.
- **Deadline for dossier submissions.** To assist our planning of dossier submissions, we would kindly ask for an early notification of the proposed submission dates.
- **Extension of Annex I inclusion.** We understand that consideration is being given to extending the Annex I inclusion period for the substances listed above in order to ensure that adequate time for the submission and evaluation of these substances and compliance with the new Regulation is granted. We would welcome such a move and early information about the possible extension would be appreciated.

Given the number of substances listed above, we would welcome the opportunity to discuss with you the possibility of a programme of submission to ensure a staggered and manageable workload.

We would be grateful if you could confirm receipt of the notification and let us know the scope of further action we need to implement in order to renew the approval of all the notified active substances.

We are looking forward to receiving your guidance on these matters, including who our contact should be with regard to the progression of this application.