



Roma, 25 luglio 2014

Ministero della Salute

**DIREZIONE GENERALE PER L'IGIENE E
LA SICUREZZA DEGLI ALIMENTI E
DELLA NUTRIZIONE
Uff. VII DGSAN**

AGROFARMA

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To ALL THE REGISTRATION
HOLDERS

**OGGETTO: REQUEST FOR INFORMATION: PRODUCTS CONTAINING 'AIR2'
ACTIVES TO BE SUPPORTED AT ARTICLE 43 RENEWAL**

Dear authorisation holder

You will be aware that following renewal of approval for the 'AIR2' active substances¹ (listed in the Annex of the present note), the process of Article 43 (the renewal of authorisations for all products containing those active substances) will begin. Whilst the procedures for Article 43 renewal are not yet fully determined, it is clear that the renewal process will represent a significant demand on resources for both industry and MS regulators.

Article 43 is defined as a 'zonal' process, thus the principles of MS co-operation will be fundamental to the implementation of the procedure. To help the South Zone MS's to plan for the expected workloads, we ask all affected authorisation holders to provide some information to facilitate co-operative working between MS. We have designed a simple spreadsheet to collect this information, available via [CIRCABC](#).

Note this letter/email has been sent by each South Zone MS to all affected authorisation holders in that MS. Whilst you may reply to each individual MS, we note that multinational companies (or company holding, for the same product, authorizations in different MSs) may prefer to collate their responses at the zonal level and send the information to a common contact in the South zone. Please see below for details.

Please complete this spreadsheet, including as much information as possible for **each of your products containing an AIR 2 active substance**. We note you may not be certain at this stage whether you intend to support the product at Art 43 renewal, however we ask that you include product details even if this is a just a possibility. Authorisation holders need not include 'clone' (back-to-back) products which are based fully on letters of access, but 'generic' products *should*

¹ for details of the active substances please see Regulation 1141/2010

be included. Please do not delete any columns, simply leave them blank if they do not apply. Note you need not respond for products that do not contain an AIR 2 active substance.

Send the completed spreadsheet to dgsan@postacert.sanita.it, *and*, if you represent a multinational company providing information across a number of MS, to syg61@minagric.gr by, 30 September 2014.

Thank you for your co-operation in this matter.

Best regards

Signed IL DIRETTORE GENERALE
dr. Silvio BORRELLO

List of active substances referred to in Article 1 and their rapporteur Member States (RMS), co-rapporteur Member States (Co-RMS) and of the final dates for submission of dossiers

Column A		Column B	Column C	Column D
Substance		New RMS	Co-RMS	Deadline for submission of dossier
2,4-D	2012	EL	PL	29 February 2012
Amitrole	2011	FR	HU	29 February 2012
Esfenvalerate	2011	UK	PT	29 February 2012
Flumioxazine	2012	CZ	FR	29 February 2012
Lambda-Cyhalothrin	2011	SE	ES	29 February 2012
Acibenzolar-s-methyl	2011	FR	ES	29 February 2012
Bentazone	2011	NL	DE	29 February 2012
Cyclanilide	2011	AT	EL	29 February 2012
Fenhexamid	2011	UK	IT	29 February 2012
Ferric phosphate	2011	DE	PL	29 February 2012
Pymetrozine	2011	DE	BE	29 February 2012
Flupyr-sulfuron-methyl	2011	FR	DK	31 May 2012
Diquat	2011	UK	SE	31 May 2012
Glyphosate	2012	DE	SK	31 May 2012
Iprovalicarb	2012	IE	IT	31 May 2012
Paecilomyces fumosoroseus	2011	BE	NL	31 May 2012
Thiabendazole	2011	ES	NL	31 May 2012
Pyridate	2011	AT	LV	31 May 2012
Sulfosulfuron	2012	SE	IE	31 May 2012
Pyraflufen-ethyl	2011	NL	LT	31 May 2012
Prosulfuron	2012	FR	SK	31 May 2012
Thifensulfuron-methyl	2012	UK	AT	31 August 2012
Cinidon-ethyl	2012	HU	UK	31 August 2012
Cyhalofop butyl	2012	IT	AT	31 August 2012
Florasulam	2012	PL	BE	31 August 2012
Metalaxyl-M	2012	BE	EL	31 August 2012
Picolinafen	2012	DE	LV	31 August 2012
Isoproturon	2012	DE	CZ	31 August 2012
Metsulfuron methyl	2011	SI	SE	31 August 2012
Triasulfuron	2011	FR	DK	31 August 2012
Famoxadone	2012	UK	FI	31 August 2012