MINISTRY OF AGRICULTURE, WATER RESOURCES AND FISHING

Decree n° 2010-2973 dated 15 November 2010, amending and completing decree n° 92- 2246 dated 28 December 1992, fixing the methods and conditions of obtaining the approval, the provisional authorizations of sale of the pesticides of agricultural use, as well as the conditions of their manufacture, importation, formulation, conditioning, storage, sale, distribution and the conditions of use of the pesticides of extremely dangerous agricultural use.

The President of the Republic,

On a proposal from the Minister of Agriculture, Water Resources and Fishing,

Having regard to law n° 92-72 dated 3 August 1992, reviewing the legislation relating to the protection of plants, as completed by law n° 99-5 dated 11 January 1999 and amended by law n° 2001-28 dated 19 March 2001, simplifying the administrative procedures in the sector of agriculture and fishing,

Having regard to decree n° 92-2246 dated 28 December 1992, fixing the methods and conditions of obtaining the approval, the provisional authorizations of sale of the pesticides of agricultural use, as well as the conditions of their manufacture, importation, formulation, conditioning, storage, sale, distribution and the conditions of use of the pesticides of extremely dangerous agricultural use, as amended by decree n° 2002-3469 dated 30 December 2002,

Having regard to decree n° 93-1145 dated 17 May 1993, fixing the amount and methods of perception of the

contribution relating to the phyto-sanitary control operations of analysis, approval and provisional authorizations of sale of pesticides, as amended by decree n° 2008-3615 dated 21 November 2008,

Having regard to the decree n° 2001-419 dated 13 February 2001, fixing the attributions of the Ministry of Agriculture,

Having regard to the decree n° 2005-1991 dated 11 July 2005, relating to the impact studies on the environment and fixing the categories of units subjected to the impact study on the environment and the categories of units subjected to the specifications,

Having regard to decree n° 2010-72 dated 14 January 2010, appointing the Government members,

Having regard to the opinion of the Minister of Public Health,

Having regard to the opinion of the Minister of Environment and Sustainable Development,

Having regard to the opinion of the Minister of Trade and Handicrafts,

Having regard to the opinion of Minister of Industry and Technology,

Having regard to the opinion of the Administrative Tribunal.

Decrees the following:

Article one - Is repealed article 5 of the decree n° 92-2246 dated 28 December 1992 referred to above and replaced by the following provisions:

Article 5 (new): To obtain the approval or the provisional authorization of sale of the pesticides of agricultural use, any applicant shall address to the Minister of Agriculture, Water Resources and Fishing a file including:

- 1 A form delivered by the administration and duly filled by the applicant.
- 2 For the imported pesticides, the original of the certificate of approval of the pesticide delivered by the official authorities of the country of origin or an authenticated copy certified valid by the embassy of Tunisia of the country of origin and mentioning that the pesticide to be approved is used and in the course of use in the country of origin at the date of the application.
- 3 The designation of the uses of the pesticide subject of the request for approval.
- 4 The final model of the notice of use of the product with indication of the amounts, the recommended periods of application and the precautions required by its employment with mention of the antidote if it exists.
 - 5 A sample of the proposed packing.
- 6 A file relating to the effectiveness of the product and its harmlessness for the cultures and harvested products.
- 7 For the pesticides of origin, a study of reference relating to the toxicity of the pesticides with respect to the man and the environment and emanating from the manufacturer of origin. For the generic pesticides, an original file which relates to the study of the different types

of toxicity of the active substance and the product formulated with respect to the man and the environment, the residues of these substances, their outcome in the agricultural products, the ground and water and their effects on the environmental systems, this original file shall contain recent information according to the international standards applied in this field and delivered by specialized and internationally accredited laboratories.

- 8 A file relating to the methods of analyses of the active substance and residues.
- 9 A sample of the pure active substances (analytical standard) accompanied by the original of the bulletin of the analyses delivered by specialized laboratories.
- 10 For the imported pesticides, a sample of the pesticide to be marketed prepared in the packing of origin used in the country of origin which is sealed, different batches and available in sufficient quantity to carry out the laboratory analyses and the field experiments.
- 11 A detailed bulletin of analysis mentioning the composition of the pesticide, including the active substance, the additives, the solvents, the impurities and others, delivered by specialized internationally accredited laboratories on the matter and accompanied by a safety card for all the mentioned components.

The administration may, if necessary, carry out all the types of chemical analyses and all measurements necessary to check the exactitude of provided information.

12 - A receipt of the royalty payment relating to the request of approval.

The Minister of Agriculture, Water Resources and Fishing notifies to the applicants his agreement or his refusal of grant of the approval or provisional authorization of sale of the pesticides of agricultural use after opinion of the technical commission provided for in article 16 of law n° 92-72 dated 3 August 1992 referred to above.

The validity period of the provisional authorization of sale is of one year renewable only once.

The approval duration is fixed at ten years renewable at the request of the concerned person, and this, three months before the expiry of the duration referred to above.

The technical commission referred to above may revise the grant of the approval of any pesticide subsequent to the evolution of the scientific innovations relating to the medical and environmental impacts of the active substances or the additives or the solvents or the impurities or the residues.

Art. 2 - The concerned persons shall benefit from a sixmonth period to present the files and the documents required for the pesticides which obtained the approval before the entry into force of the decree herein.

The imported quantities of the pesticides whose related approval is withdrawn shall be liquidated within a deadline not exceeding one year as of the date of the notification of the withdrawal of the approval.

Art. 3 - The Minister of Agriculture, Water Resources and Fishing, the Minister of Public Health, the Minister of Environment and Sustainable Development, the Minister of Trade and Handicrafts and the Minister of Industry and

Technology, each in his respective capacity, shall implement the decree herein which shall be published in the Official Gazette of the Republic of Tunisia.

Tunis, 15 November 2010.

Zine El Abidine Ben Ali