L.N. 314 of 2010

PESTICIDES CONTROL ACT
(CAP. 430)

Biocides (Amendment) (No. 2) Regulations, 2010

IN exercise of the powers conferred by articles 4 and 5 of the Pesticides Control Act, the Minister for Resources and Rural Affairs, in consultation with the Prime Minister and with the Minister for Health, the Elderly and Community Care, has made the following regulations :-

Title and scope.

1. (1) The title of these regulations is the Biocides (Amendment) (No. 2) Regulations, 2010 and they shall be read and construed as one with Biocides Regulations, 2004, hereinafter referred to as "the principal regulations".

L.N. 294 of 2004.

(2) The scope of these regulations is to transpose Commission Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods.

Amends regulation 47 of the principal regulations.

2. Regulation 47 of the principal regulations shall be amended as follows:

(a) In sub-regulation (1) thereof, for paragraph (c) there shall be substituted the following:

"(c) in the case of a biocidal product containing an active substance already on the market on May 14, 2000:

(i) until 14 May 2014 for any information submitted for the purposes of these regulations, except where such information is already protected under existing national rules relating to biocidal products. In such cases, the information shall continue to be protected until the expiry of any remaining period of data protection provided for

under national rules, but not beyond 14 May 2014 or, if applicable, not beyond the date to which the transitional period referred to in regulation 50(1) is extended in accordance with regulation 50(2);

(ii) for a period of 10 years from the date of entry of an active substance into Parts I or IA of the Register of active substances for information submitted for the first time in support of the first inclusion in Parts I or IA of the Register of active substances of either the active substance or an additional product type for that active substance,"; and

(b) In sub-regulation (2) thereof, for paragraph (c) there shall be substituted the following:

"(c) in the case of a biocidal product containing an active substance already on the market on May 14, 2000:

(i) until 14 May 2014 for any information submitted for the purposes of these regulations, except in the case where data are already protected according to existing national rules relating to biocidal products, in which case such data shall be protected nationally until the expiry of any remaining period of data protection provided for under those national rules, but not beyond 14 May 2014 or, if applicable, not beyond the date to which the transitional period referred to in regulation 50(1) is extended in accordance with regulation 50(2);

(ii) for a period of 10 years form the date of entry of an active substance onto Parts I or IA of the Register of active substances, for information which is submitted for the first time in support of the inclusion in Parts I or IA of the Register of active substances either of the active substance or of an additional product type for that active substance;".

3. Immediately after regulation 49 of the principal regulations there shall be added the following new regulation:

Adds new regulation 50 to the principal regulations.

"Transitory provisions.

50. (1) By way of further derogating from the second proviso to regulation 2(5), 4(1)(b) and (d), 9(2) and 17(1) and (4), and without prejudice to sub-regulations (2) and (3) of this regulation, the Director may, until 14 May 2014, continue to apply its current system or practice of placing biocidal products on the market. If a decision to include an active substance in Parts I or IA of the Register of active substances sets a later date than 14 May 2014 for compliance with regulation 50(3), this derogation shall continue to apply for products including that active substance until the date set in that decision. In accordance with national rules, the Director may authorise the placing on the market of a biocidal product containing active substances not listed in Parts I or IA of the Register of active substances for that product type. Such active substances shall be on the market on May 14, 2000 as active substances of a biocidal product for purposes other than "scientific research and development" and "process-oriented research and development" as defined in regulation 3(1) hereof.

(2) Following the adoption of these regulations, and after the Commission has commenced a 14-year work programme for the systematic examination of all active substances already on the market on May 14, 2000 as active substances of a biocidal product for purposes other than "scientific research and development" and "process-oriented research and development" as defined in regulation 3(1), and from May 14th 2000, it be decided that an active substance will be included in Parts I, IA or IB the Register of active substances and under which conditions, or, in cases where the requirements of regulations 4(3), (4), (5), (7) and (8), 5(1), 6(2) are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Parts I, IA or IB of the Register of active substances.

(3) Following such a decision to include or not to include an active substance in Parts I, IA or IB

of the Register of active substances, it shall be ensured that authorisations or, where relevant, registrations for biocidal products containing the active substances and complying with the provisions of these regulations are granted, modified or cancelled as appropriate.”.

Ippubblikat mid-Dipartiment tal-Informazzjoni (doi.gov.mt) — Valletta — ***Published by the Department of Information (doi.gov.mt) — Valletta***
Mitbugħ fl-Istamperija tal-Gvern fuq karta riċiklata — ***Printed at the Government Printing Press on recycled paper***

Prezz/*Price*
€0.37