Suppliment tal-Gazzetta tal-Gvern ta' Malta Nru. 18,600, 28 ta' Mejju, 2010

Taqsima B

A.L. 314 tal-2010

ATT DWAR IL-KONTROLL TAL-PESTIĊIDI (KAP. 430)

Regolamenti ta' l-2010 li jemendaw ir- Regolamenti dwar il-Bijoċidi (Emenda Num. 2)

BIS-SAĦĦA tas-setgħat mogħtija bl-artikoli 4 u 5 ta' l-Att dwar il-Kontroll tal-Pestiċidi, il-Ministru għar-Riżorsi u Affarijiet Rurali, wara li kkonsulta lill-Prim Ministru u lill-Ministru għas-Saħħa, l-Anzjani u Kura fil-Komunita, għamel dawn ir-regolamenti li ġejjin:-

Titolu u skop.

1. (1) It-titolu ta' dawn ir-regolamenti hu Regolamenti ta' l-2010 li jemendaw ir-Regolamenti dwar il-Bijoċidi (Emenda Num. 2), u għandhom jinqraw u jiftiehmu bħala ħaġa waħda mar-Regolamenti ta' l-2004 dwar il-Bijoċidi, hawn iżjed 'il quddiem imsejħin "ir-regolamenti prinċipali".

A.L. 294 ta' l- 2004.

(2) L-iskop ta' dawn ir-regolamenti hu li jitrassponu d-Direttiva tal-Kummissjoni 2009/107/KE tas- 16 ta' Settembru 2009 li temenda d-Direttiva 98/8/KE dwar it-tqegħid fis-suq tal-prodotti bijoċidali fir-rigward tal- estensjoni ta' ċerti perjodi ta' żmien.

Jemenda regolament 47 tar-regolamenti prinċipali.

2. Ir - regolament 47 tar-regolamenti principali għandu jiġi amendat kif ġej:

(a) Fis-subregolament (1) tiegħu, minflok il - paragrafu (ċ) għandu jidħol dan li ġej:

"(ċ) fil-każ ta' prodott bijoċidali li fih sustanza attiva diġà fis-suq fl-14 ta' Mejju, 2000:

(i) sal-14 ta' Mejju 2014 għal kull informazzjoni li tingħata għall-iskopijiet ta' dawn

ir-regolamenti, għajr għal meta dik l-informazzjoni tkun diġà protetta permezz tar-regoli nazzjonali eżistenti li jirrigwardaw il-prodotti bijoċidali. F'dawk il-każijiet, l-informazzjoni għandha tibqa' tiġi protetta sat-tmiem ta' kull perjodu li jkun fadal għall-protezzjoni tad-data kif previst mir-regoli nazzjonali, iżda mhux wara l-14 ta' Mejju 2014 jew, jekk dan ikun japplika, mhux wara d-data sa meta ġie estiż il-perjodu transitorju msemmi fir-regolament 50(1) b'konformità mar-regolament 50(2);

(ii) għal perijodu ta' 10 snin mid-data tad-dħul ta' sustanza attiva f'Partijiet I jew IA tar-Reġistru ta' sustanzi attivi għal informazzjoni ppreżentata l-ewwel darba biex issostni l-ewwel inklużjoni fil- Partijiet I jew IA tar-Reġistru ta' sustanzi attivi jew tas-sustanza attiva jew ta' tip ta' prodott addizzjonali għal dik is-sustanza attiva;" u

(b) Fis - subregolament (2) tiegħu, minflok il - paragrafu (ċ) għandu jidħol dan li ġej:

"(ċ) fil-każ ta' prodott bijoċidali li fih sustanza attiva diġà fis-suq fl-14 ta' Mejju, 2000:

(i) sal-14 ta' Mejju 2014 għal kull informazzjoni li tingħata għall-iskopijiet ta' dawn ir-regolamenti, għajr għal meta d-data tkun diġà protetta permezz tar-regoli nazzjonali eżistenti li jirrigwardaw il-prodotti bijoċidali, f'dak il - każ dawk id - data għandhom jibqgħu jiġu protetti sat-tmiem ta' kull perjodu li jkun fadal għall-protezzjoni tad-data kif previst fir-regoli nazzjonali, iżda mhux wara l-14 ta' Mejju 2014 jew, jekk dan ikun japplika, mhux wara d-data sa meta jkun ġie estiż il-perjodu transitorju msemmi fir-regolament 50(1) b'konformità mar-regolament 50(2);

(ii) għal perijodu ta' 10 snin mid-data tad-dħul ta' sustanza attiva f'Partijiet I jew IA tar-Reġistru ta' sustanzi attivi, għal informazzjoni ppreżentata l-ewwel darba biex issostni l-ewwel inklużjoni fil-Partijiet I jew IA tar-Reġistru ta'

sustanzi attivi jew tas-sustanza attiva jew ta' prodott addizzjonali għal dik is-sustanza attiva;".

Iżid ir-regolament 50 ġdid mar-regolamenti prinċipali.

3. Minnufih wara r-regolament 49 tar-regolamenti prinċipali għandu jiżdied dan ir-regolament ġdid li ġej:

"Dispożizzjoni transitorji.

50. (1) B'deroga oħra mit-tieni proviso li hemm mar - regolament 2(5), 4(1)(b) u (d), 9(2) u 17(1) u (4), u mingħajr preġudizzju għas - subregulamenti (2) u (3) ta' dan ir-regolament, id-Direttur jista', sal-14 ta' Mejju 2014, ikompli japplika s-sistema jew il-prattika attwali tiegħu li jqiegħed fis-suq il-prodotti bijoċidali. Jekk deċiżjoni sabiex sustanza attiva tiġi inkluża f'Partijiet I jew IA tar-Reġistru ta' sustanzi attivi tkun tistabbilixxi data iktar tard mill-14 ta' Mejju 2014 għal konformità mar-regolament 50(3), din id-deroga għandha tibqa' tapplika għal prodotti li jkunu fihom dik is-sustanza attiva sad-data stabbilita f'dik id-deċiżjoni. Skond ir-regoli nazzjonali tiegħu, id-Direttur jista' jawtorizza t-tqegħid fis-suq ta' prodott bijoċidali li jkun fih sustanzi attivi li mhux elenkati f'Partijiet I jew IA tar-Reġistru ta' sustanzi attivi għal dak it-tip ta' prodott. Dawk is-sustanzi attivi għandhom ikunu fis-suq fl-14 ta' Mejju, 2000 bħala sustanzi attivi ta' prodott bijoċidali għal finijiet oħra għajr dawk ta' "riċerka u żvilupp xjentifiku" u "riċerka u żvilupp orjentat lejn il-proċess" kif inhuma mfissra fir-regolament 3(1) ta' dawn ir – regolamenti.

(2) Wara l-adozzjoni ta' dawn ir-regolamenti, u wara li l- Kummissjoni tkun bdiet programm ta' ħidma ta' 14-il sena għall-eżami sistematiku tas-sustanzi attivi kollha li diġà qegħdin fis-suq fl-14 ta' Mejju, 2000 bħala sustanzi attivi ta' prodott bijoċidali għal skopijiet oħra differenti minn dawk ta' "riċerka u żvilupp xjentifiku" u "riċerka u żvilupp orjentat lejn il-proċess" kif imfissra fir-regolament 3(1), u mill- 14 ta' Mejju 2000, sustanza attiva tista' tiġi inkluża fil-Partijiet I, IA jew IB tar-Reġistru ta' sustanzi attivi u taħt liema kundizzjonijiet, jew, f'każi jew meta il-kundizzjonijiet tar-regolamenti 4(3), (4), (5), (7) u (8), 5(1), 6(2) ma jkunux sodisfatti jew l-informazzjoni meħtieġa u d-data ma jkunux ġew ippreżentati fiż-żmien stipulat, li dik is - sustanza attiva m'għandiex tiġi inkluża fil-Partijiet I, IA jew IB tar-Reġistru ta' sustanzi attivi.

(3) Wara dik id-deċiżjoni sabiex tiddaħal jew le sustanza attiva fil-Partijiet I, IA jew IB tar-Reġistru ta' sustanzi attivi, għandu jiġi żgurat illi jiġu konċessi, modifikati jew imħassra kif adatt l-awtorizzazzjonijiet jew, skond ma jkun rilevanti, ir-reġistrazzjonijiet għal prodotti bijoċidali li jkun fihom is-sustanzi attivi u li jkunu jħarsu d-dispozzizzjonijiet ta' dawn ir-regolamenti.".

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.”.

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