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Carbendazim for use in certain biocidal products

European Parliament resolution of 26 November 2020 on the draft Commission implementing regulation approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10 (D069099/01 — 2020/2852(RSP))

(2021/C 425/10)

The European Parliament,

— having regard to the draft Commission implementing regulation approving carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10 (D069099/01,

— having regard to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ([1]),

— having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([2]), and in particular the third subparagraph of Article 89(1) thereof,

— having regard to Article 11 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers ([3]),

— having regard to Rule 112(2) and (3) of its Rules of Procedure,

— having regard to the motion for resolution of the Committee on the Environment, Public Health and Food Safety,

A. whereas the draft Commission implementing regulation seeks to approve carbendazim as an existing active substance for use in biocidal products of product-type 7 (film preservatives) and product-type 10 (masonry preservatives), for a period of three years;

B. whereas the Commission has committed to a zero-pollution ambition to attain a toxic-free environment to help protecting citizens and the environment better against hazardous chemicals and encourage innovation for the development of safe and sustainable alternatives;

C. whereas the assessment reports and the conclusions of the Rapporteur Member State in relation to carbendazim were submitted to the Commission on 2 August 2013; whereas it can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC;

D. whereas the hazardous properties of carbendazim were already known in 2013 when the assessment reports were submitted by the Rapporteur Member State; whereas seven years have passed between the submission of the assessment reports and the draft Commission implementing regulation;

Legal arguments

Unacceptable risk to the environment

E. whereas the approval of carbendazim for use in product-types 7 and 10 could lead to unacceptable risks to the environment and human health in contravention of Directive 98/8/EC;

([1]) OJ L 123, 24.4.1998, p. 1.
([2]) OJ L 167, 27.6.2012, p. 1.
([3]) OJ L 55, 28.2.2011, p. 13.

F. whereas carbendazim meets the criteria for classification as mutagen category 1B and reproductive toxicant category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]) and two of the persistent, bio-accumulative and toxic (PBT) criteria (P and T);

G. whereas concerns have also been raised in multiple studies regarding the endocrine-disrupting potential of carbendazim ([5]); whereas according to opinions of the Biocidal Products Committee (BPC) on carbendazim for all product-types 7, 9 and 10 ([6]), no conclusion could be drawn regarding the endocrine-disrupting properties; whereas it is very concerning that the Commission continues to disregard the precautionary principle by proposing to authorise active substances as a result of inconclusive assessments of their endocrine-disrupting properties based on available data; whereas being unable to conclude on endocrine-disrupting properties of a substance based on limited data availability is not equivalent to concluding that that substance has no endocrine-disrupting properties;

H. whereas although the assessment reports in relation to carbendazim were submitted before 1 September 2013, meaning that 'though carbendazim fulfils Article 5(1)(b) and (c) of Regulation (EU) No 528/2012, Article 5(2) of Regulation (EU) No 528/2012 is not of relevance for the approval decision' ([7]), the fact that carbendazim has known hazardous properties of very high concern is still highly relevant and was not sufficiently taken into account in the implementation of Directive 98/8/EC, considering Article 10 read in conjunction with Article 5(1)(b) of that Directive;

I. whereas the use of carbendazim in product-types 7 and 10 in the treatment of outdoor paints for facades to avoid fungal and algal growth poses a high risk of water pollution due to the run-off of those biocides from the facades of buildings each time it rains;

J. whereas a study ([8]) has concluded that, in Germany, carbendazim was found in more than 90 % of the samples from rainwater clarifiers and in more than 50 % of samples from storm water overflow basins, which release untreated rainwater into water bodies or leach into groundwater;

K. whereas the BPC opinion for product-type 9 (fibre, leather, rubber and polymerised materials preservatives) concluded that carbendazim was not approved for the very reason that leaching of carbendazim from treated surfaces with rainwater results in unacceptable risks in the surface water and sediment compartments and that no adequate risk management measure is available;

([4]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([5]) Morinaga, H. et al., 'A Benzimidazole Fungicide, Benomyl, and Its Metabolite, Carbendazim, Induce Aromatase Activity in a Human Ovarian Granulose-Like Tumor Cell Line (KGN)', Endocrinology 2004, 145(4):1860–1869; Kim, D-J. et al., 'Benomyl induction of brain aromatase and toxic effects in the zebrafish embryo', Journal of Applied Toxicology 2009, 29:289–294; Goldman, J.M. et al., 'Effects of the benomyl metabolite, carbendazim, on the hypothalamic-pituitary reproductive axis in the male rat', Toxicology 1989, 57(2): 173-182; Jiang, J. et al, 'Carbendazim has the potential to induce oxidative stress, apoptosis, immunotoxicity and endocrine disruption during zebrafish larvae development', Toxicology in Vitro 2015, 29(7):1473-1481; Singh, S., Singh, N., Kumar, V. et al., 'Toxicity, monitoring and biodegradation of the fungicide carbendazim', Environmental Chemistry Letters 2016, 14: 317–329; Jin, C., Zeng, Z., Wang, C., Luo, T., Wang, S., Zhou, J., Ni, Y., Fu, Z., Jin, Y., 'Insights into a Possible Mechanism Underlying the Connection of Carbendazim-Induced Lipid Metabolism Disorder and Gut Microbiota Dysbiosis in Mice', Toxicological Sciences 2018, 166(2): 382-393; Durand, P., Martin, G., Blondet, A., Gilleron, J., Carette, D., Janczarski, S., Christin, E., Pointis, G., Perrard, M.H., 'Effects of low doses of carbendazim or iprodione either separately or in mixture on the pubertal rat seminiferous epithelium: An ex vivo study', Toxicology In Vitro 2017, 45(3):366-373; Jin, Y., Zeng, Z., Wu, Y., Zhang, S., Fu, Z., 'Oral Exposure of Mice to Carbendazim Induces Hepatic Lipid Metabolism Disorder and Gut Microbiota Dysbiosis', Toxicological Sciences 2015, 147 (1):116-26; Rama, E.M., Bortolan, S., Vieira, M.L., Gerardin, D.C., Moreira, E.G., 'Reproductive and possible hormonal effects of carbendazim', Regulatory Toxicology and Pharmacology 2014, 69(3):476-486.

([6]) BPC opinion of 10 December 2019 on the application for approval of the active substance: Carbendazim, Product type: 7; BPC opinion of 27 February 2019 on the application for approval of the active substance: Carbendazim, Product type: 9; BPC opinion of 10 December 2019 on the application for approval of the active substance: Carbendazim, Product type: 10; https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval?diss=true&-search_criteria_ecnumber=234-232-0&search_criteria_casnumber=10605-21-7&search_criteria_name=Carbendazim

([7]) BPC opinions for product-types 7 and 10, p. 14.

([8]) https://www.umweltbundesamt.de/sites/default/files/medien/479/ publikationen/texte_169-2020_belastung_der_umwelt_mit_bioziden_realistischer_erfassen_-_schwerpunkt_eintraege_ueber_klaeranlagen.pdf

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L. whereas the BPC opinions for product-types 7 and 10 concluded that the outdoor uses of carbendazim, including paints (product-type 7) and plasters (product-type 10), pose an unacceptable risk in the surface water and sediment compartments since no adequate risk mitigation measure is available to avoid releases in the sewer over the service lifetime (five years for product-type 7 and 25 years for product-type 10) of treated articles;

M. whereas the approval of carbendazim for use in product-types 7 and 10, even for a short period of three years, would therefore result in direct discharge of carbendazim in the environment through rainwater for a period of up to 25 years;

N. whereas Sweden stated in its minority opinion to BPC that leaching during the in-service life of applied products and treated articles (e.g. paints and plaster) for all outdoor uses poses unacceptable risks to the environment, and that this risk could not be mitigated according to the assessment report;

O. whereas the fact that the BPC opinions conclude that the use of carbendazim in, respectively, product-types 7, 9 and 10 present the same unacceptable risks should have led to a decision not to approve carbendazim for all of these outdoor uses, and not only for product-type 9;

P. whereas indoor uses of carbendazim may also present unacceptable risks, because studies ([9]) have raised concerns that the occurrence of carbendazim in surface water comes mainly from the discharge of treated domestic and industrial wastewater, despite the BPC opinions' conclusion that the risks to the environment from indoor uses of carbendazim are acceptable;

Approval conditions failing to mitigate the risks

Q. whereas, in view of the risks to the environment identified for the uses assessed, according to the draft Commission implementing regulation, carbendazim may be approved provided that certain specifications and conditions concerning its use are complied with, in particular that the product assessment shall 'pay particular attention' to surface water, sediment, soil and groundwater for products used in paints or plasters which are intended to be used outdoors;

R. whereas, the BPC opinions for product-types 7 and 10 both point out unacceptable risks in the surface water and sediment compartments, and indicate that, for the uses assessed, no adequate risk management measure to avoid releases in the sewer is available;

S. whereas the Commission's call for 'specifications and conditions' attached to the authorisation is extremely vague and does not suffice to alleviate the concerns of unacceptable risks; whereas the draft Commission implementing regulation does not require Member States to prescribe adequate risk mitigation measures, but simply to pay attention to risks; whereas the draft Commission implementing regulation does not take into account the fact that the supporting documents concluded that there are no adequate risk management measures available;

Coherence between the risk management decision and scientific evidence relied upon

T. whereas, and as confirmed by the Court of Justice of the European Union ('the Court'), when adopting a risk management measure, the decision made by the Commission must be coherent with the scientific evidence relied upon; whereas the Commission may disregard a scientific opinion delivered during the decision-making process, but it must then provide specific reasons for its findings, of equivalent scientific value, by comparison with those made in the opinion; whereas its statement of reasons must explain why it is disregarding the opinion ([10]);

U. whereas the decision to approve carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10 significantly contradicts the conclusion of the BPC opinions that outdoor uses of carbendazim in paints (product-type 7) and plasters (product-type 10) pose unacceptable risks in the surface water and sediment compartments considering Article 10 of Directive 98/8/EC read in conjunction with Article 5(1)(b) of that Directive;

([9]) Merel, S., Benzing, S., Gleiser, C., Di Napoli-Davis, G., Zwiener, C., 'Occurrence and overlooked sources of the biocide carbendazim in wastewater and surface water', Environmental Pollution 2018, 239:512-521.

([10]) See Case T-837/16, *Sweden v. Commission,* ECLI:EU:T:2019:144, paragraph 69.

V. whereas the reasons to depart from the conclusion of the BPC opinions that the Commission provides in its draft implementing regulation are limited to the arguments that the full authorisation of biocidal products requires an additional step at Member State level and that the review under Regulation (EU) No 528/2012 will be carried out soon;

W. whereas those reasons do not explain why the Commission considered that carbendazim does not present an unacceptable risk for uses in product-types 7 and 10 under Directive 98/8/EC, in particular given that the use of the same active substance in product-type 9 was considered to present an unacceptable risk, which led to the decision not to grant authorisation for that product-type;

X. whereas a statement of the reasons for departing from the conclusions of the BPC opinions is not only indispensable for the control of the Court, but also more specifically for Parliament to be able to exercise its power of scrutiny properly;

Consideration of available alternatives

Y. whereas according to the BPC opinion for product-type 7, carbendazim is intended to be used as a fungicide in biocidal film preservative products that are applied to, or incorporated into, end-applications like paints; whereas according to the BPC opinion for product-type 10, carbendazim is to be used as a fungicide in construction material preservatives that are applied to, or incorporated into, end-products like plasters;

Z. whereas the Commission concluded that no suitable alternatives to carbendazim are available based only on eleven non-confidential contributions from third parties, all of them companies or industrial associations, and dating back to 2014; whereas, if other information is available to support the decision of the Commission, it should be made available to Parliament to enable it to exercise fully its power of scrutiny;

AA. whereas, according to the BPC opinions, most contributions did not differentiate between the uses of carbendazim in product-types 7, 9 and 10, thereby not allowing the Commission to assess properly the availability of alternatives for each of the separate product-types and uses;

AB. whereas the information provided in the contributions is far from being sufficiently detailed and up-to-date to conclude that there is an absence of suitable alternatives to carbendazim for use in biocidal products of product-types 7 and 10;

AC. whereas, in particular for product-type 7, contributors declared that a replacement of carbendazim in paints is technically possible, although they deemed it too time-consuming and too costly;

AD. whereas, in particular for product-type 10, contributors declared that a replacement of carbendazim in paints is technically possible, although they deemed it too time-consuming and too costly; whereas, according to the BPC opinion, due to the very low number of approved active substances for that product-type, information available for the BPC is currently not sufficient to decide whether there is any other active substance that could provide an alternative to the use of carbendazim as a preservative in plasters characterised by a high pH value;

AE. whereas most of the contributions submitted to the Commission in 2014 concluded that finding alternatives to carbendazim for product-types 7 and 10, although not without difficulties, was possible;

AF. whereas applicants have had seven years to investigate potential alternatives to carbendazim, of which harmful properties are well known;

AG. whereas the Commission, therefore, has failed to uphold its duty of considering the availability of suitable alternative substances in accordance with Article 10(5) of Directive 98/8/EC; whereas no explanation have been provided to specify in detail on which basis the Commission concluded that suitable and sufficient alternative substances were unavailable; whereas such details are of great importance for the outcome of the present authorisation considering the toxicological profile of the substance;

AH. whereas uses of carbendazim in product-type 9 were not granted approval; whereas none of the information received and referred to in the BPC opinion was specific for product-type 9; whereas the same concerns were raised by third party contributors regarding the limited number of alternatives available as well as the time and costs necessary to develop an alternative with an equivalent level of effectiveness to carbendazim for product-type 9 as for product-types 7 and 10;

AI. whereas, according to the BPC opinions for both product-types 7 and 10, contributors have pointed out that it is difficult to assess the availability of alternatives, given that many of them still have to be reviewed under Regulation (EU) No 528/2012; whereas it is unacceptable that the delay in the delivery of the review programme should serve as a justification to hinder the protection of human health and the environment;

Political arguments

AJ. whereas it is unacceptable that the Commission decides to postpone the non-approval of substances that present an unacceptable risk to human health and the environment, with the mere justification that Regulation (EU) No 528/2012 will help making such non-approval more systematic through future reviews;

AK. whereas the draft Commission implementing regulation provides that pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities of the Member States should evaluate whether the conditions of Article 5(2) of that Regulation can be satisfied in their territories in order to decide whether a biocidal product containing carbendazim can be authorised;

AL. whereas the Commission should not be delegating the responsibility for refusing the marketing of biocidal products containing carbendazim to Member States, based on the argument that the information received during the public consultation for potential candidates for substitution is of low quality;

AM. whereas, as proposed by the Commission, only a label providing limited information will be required to appear on treated articles and that label will not be subject to regulatory scrutiny before the article is placed on the market and traded between Member States; whereas, since no product authorisation is necessary, there will be no evaluation of whether the efficacy of the product matches the label claims;

AN. whereas this situation does not provide a high enough level of protection of human health and the environment, and also does not provide a level playing field for Union and non-Union companies;

1. Considers that the draft Commission implementing regulation is not consistent with Union law, in that it is not compatible with the aim and content of Directive 98/8/EC or Regulation (EU) No 528/2012;

2. Considers, in view of

(a) the hazardous properties of carbendazim,

(b) its environmental fate, as well as the lack of risk management measures stated in the supporting documents,

(c) the lack of data to decisively conclude on the absence of suitable alternatives,

(d) the seven-year period that has passed since the submission of the assessment reports, and

(e) the lack of coherence between the Commission decisions on the uses of carbendazim in product-types 7, 9 and 10,

that the draft Commission implementing regulation to approve carbendazim as an existing active substance for use in biocidal products of product-types 7 and 10, even for a short period of three years, is not proportionate in light of the unacceptable risks it poses to human health and the environment, and should have lead the Commission to the conclusion of unacceptable risks, as the use of carbendazim in a product still gives rise to concerns;

3. Considers that the information provided by the Commission in its draft implementing regulation is insufficient for Parliament to be able to exercise its power of scrutiny properly;

4. Calls on the Commission to withdraw its draft implementing regulation and to submit a new draft to the committee, proposing not to approve carbendazim as an active substance for use in biocidal products of product-types 7 and 10;

5. Reiterates that, although the assessment reports were submitted before 1 September 2013, authorising a substance classified as mutagenic 1B, toxic for reproduction 1B, and with potential endocrine-disrupting properties poses unacceptable risks to human health in relation to uses such as those considered;

6. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.