CENTER FOR FOOD SAFETY

December 20, 2021

Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460–0001

RE: Comments on the Proposed Interim Registration Review Decision for Chlormequat Chloride: Case Number 7069

EPA Docket EPA-HQ-OPP-2015-0816

Center for Food Safety appreciates the opportunity to comment on the above-named matter on behalf of itself and its 970,000 members and supporters. Center for Food Safety (CFS) is a public interest, nonprofit membership organization with offices in Washington, D.C., San Francisco, California, and Portland, Oregon. CFS's mission is to empower people, support farmers, and protect the earth from the harmful impacts of industrial agriculture. Through groundbreaking legal, scientific, and grassroots action, CFS protects and promotes the public's right to safe food and the environment. CFS has consistently supported comprehensive EPA review of registered pesticides and individual inert ingredients.

Center for Food Safety (CFS) opposes EPA's proposed interim registration review decision for chlormequat chloride. The registration review was conducted without due consideration of several extremely significant new uses and associated tolerances that Taminco US LLC has petitioned EPA to grant. The proposed new uses of chlormequat chloride are on barley, oat, triticale and wheat grains; and the requested U.S. tolerances for this compound are for these raw agricultural commodities, as well as for the meat and meat byproducts of cattle, goats, hogs, sheep and poultry, additionally in eggs and milk. CFS has previously submitted comments on both the new uses and tolerances (both EPA-HQ-OPP-2021-0290). Those comments and supporting materials are incorporated by reference here.

INTRODUCTION

Chlormequat chloride is a plant growth regulator that inhibits gibberellic acid, a hormone that promotes plant stem elongation. Treatment leads to thicker, shorter stems. At present, chlormequat is registered for use only on ornamentals, mostly indoors in greenhouses, with limited outdoor use on containerized plants in shadehouses (EPA 3/26/21). It is not registered for use on a single crop intended for food or feed; and with usage totaling about 1,000 lbs/year nationwide (EPA 2/25/16), Americans and the nation's environment have very limited exposure to chlormequat from domestic use.

However, chlormequat is registered for use on grains in Europe, the U.K., Canada and other countries, which along with Codex have established corresponding tolerances. In fact, about 65% of winter wheat and 50% of winter barley and oats are treated with products containing chlormequat in the United Kingdom (Spink et al. 2004), while 70% of the wheat in the European Union as a whole is treated with it (Sorensen and Danielsen 2006). To facilitate import of chlormequat-treated grains from these countries, the EPA has established import tolerances that do not apply to domestically-grown grains.

Granting the requested tolerances and approving the proposed new uses will likely lead to an astronomical rise in domestic use of this chemical. Torner et al. (1999) cite typical application rates of 0.5 to 2 kg/ha (0.45 to 1.79 lbs/acre) in Europe. EPA has granted experimental use permits with permitted application rates for wheat, barley/oats, rye/triticale and grasses for seed of 1 lb/acre, 1.27 lbs/acre, 1-1.27 lbs/acre and 1.34-4 lbs/acre, respectively (EPA 3/16/21, Table 3.3, p. 11). If 70% of the U.S. wheat, oats and barley that went on to be harvested in 2020 were treated at a rate of 1 lb/acre, 28 million lbs of chlormequat would have been applied that year (40 million harvested acres in 2020 * 70% * 1 lb/acre). This would represent a 28,000-fold increase over the current 1,000 lbs/year.

RELEVANT LEGAL STANDARDS

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Under FIFRA, EPA licenses the sale, distribution, and use of pesticides, including herbicides, through the process of registration.[1] EPA can register a pesticide only upon determining that "it will perform its intended function without unreasonable adverse effect on the environment,"[2] and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[3] FIFRA defines "unreasonable adverse effects on the environment" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[4]

FIFRA's registration review process is mandated at 7 U.S.C. § 136a(g). FIFRA requires that pesticide registrations are periodically reviewed, and that EPA "shall by regulation establish a procedure for accomplishing the periodic review of registrations."[5] EPA adopted regulations pursuant to this provision in 2006, which state that each pesticide is required to be reviewed every 15 years.[6] Registration review is intended to ensure that each active ingredient's registration is based on current science, including its effects on human health and the

[1] 7 U.S.C. § 136a(5)(D).
[2] *Id.* § 136a(c)(5)(C).
[3] *Id.* § 136a(c)(5)(D).
[4] *Id.* § 136(bb).
[5] *Id.* § 136a(g)(1)(A).
[6] 40 C.F.R. §§ 155.40-155.58.

environment. If a product "fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation or other remedies under FIFRA."[7]

Endangered Species Act

As recognized by the Supreme Court, the Endangered Species Act (ESA) is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation."[8] The ESA's statutory scheme "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies."[9] Federal agencies are obliged "to afford first priority to the declared national policy of saving endangered species."[10]

Section 7(a)(2) of the ESA requires every federal agency to consult the appropriate federal fish and wildlife agency—the U.S. Fish and Wildlife Service (FWS), in the case of land and freshwater species and the National Marine Fisheries Service (NMFS) in the case of marine species—to "insure" that the agency's actions are not likely "to jeopardize the continued existence" of any listed species or "result in the destruction or adverse modification" of critical habitat.[11] The ESA's implementing regulations broadly define agency action to include "all activities or programs of any kind authorized, funded or carried out … by federal agencies," including the granting of permits and "actions directly or indirectly causing modifications to the land, water or air."[12] A species' "critical habitat" includes those areas identified as "essential to the conservation of the species" and "which may require special management considerations or protection."[13]

EPA is required to review its actions "at the earliest possible time" to determine whether the action may affect listed species or critical habitat.[14] To facilitate compliance with Section 7(a)(2)'s prohibitions on jeopardy and adverse modification, the ESA requires each federal agency that plans to undertake an action to request information from the expert agency "whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action."[15] If FWS/NMFS advises the agency that listed species or species proposed to be listed may be present, the agency must then prepare a biological assessment for the purpose of identifying any such species that are likely to be affected by the proposed agency action.[16]

If, based on a biological assessment, an agency determines that its proposed action may affect any listed species and/or their critical habitat, the agency generally must engage in

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[7] *Id*. § 155.40(a).
[8] *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 180 (1978).
[9] *Id*. at 185.
[10] *Id.*
[11] 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).
[12] 50 C.F.R. § 402.02 (emphasis added).
[13] 16 U.S.C. § 1532(5)(A).
[14] 50 C.F.R. § 402.14(a).
[15] 16 U.S.C. § 1536(c)(1); *see also* 50 C.F.R. § 402.12(c).
[16] *Id.*

formal consultation with FWS/NMFS.[17] At the end of the formal consultation, FWS/NMFS must provide the agency with a "biological opinion" detailing how the proposed action will affect the threatened and endangered species and/or critical habitats.[18] If FWS/NMFS concludes that the proposed action will jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, the biological opinion must outline "reasonable and prudent alternatives" to the proposed action that would avoid violating ESA section 7(a)(2).[19]

Pending the completion of formal consultation with the expert agency, an agency is prohibited from making any "irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures."[20]

Food Quality Protection Act

In 1996, Congress passed the Food Quality Protection Act (FQPA), which amended FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA). When determining the safety of a pesticide chemical under the FQPA, EPA "shall base its assessment of the risk posed by the pesticide chemical on aggregate (i.e., total food, drinking water, residential, and other nonoccupational) exposure to the pesticide." EPA, Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity, at 5 (Jan. 14, 2002) (emphasis in original); see 21 U.S.C. § 346a(b)(2)(A)(ii). "EPA is also required to consider available information concerning the combined toxic effects to human health that may result from dietary, residential, or other nonoccupational exposure to chemicals that have a common mechanism of toxicity." Id. (emphasis in original); see 21 U.S.C. § 346a(b)(2)(D)(v).

The Federal Food, Drug, and Cosmetic Act

Federal Food, Drug, and Cosmetic Act (the FFDCA)[21] prohibits the introduction of "adulterated" food into interstate commerce.[22] The Act requires that where use of a pesticide will result in any pesticide residue being left on food, EPA must either set a "tolerance" level for the amount of allowable pesticide residue that can be left on the food, or set an exemption of the tolerance requirement.[23]

EPA has a duty under the FFDCA to ensure that the proposed tolerance level of chlormequat residue will cause "no harm" to humans, particularly infants and children "from aggregate exposure" to chlormequat.[24] The FFDCA mandates EPA to "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator

[17] 50 C.F.R. § 402.14.
[18] 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14.
[19] 16 U.S.C. § 1536(b)(3)(A).
[20] 16 U.S.C. § 1536(d).
[21] 21 U.S.C. § 301 *et seq*.
[22] 21 US.C. § 331.
[23] 21 U.S.C. § 346a(1).
[24] 21 U.S.C. § 346a(b)(2)(A).

determines that the tolerance is safe."[25] For a tolerance level to be "safe," the statute requires EPA determine "that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[26] "Aggregate exposure" includes not only dietary exposure through food consumption, but also includes "exposures through water and residential uses."[27]

HUMAN HEALTH RISKS

Chlormequat is a low-dose reproductive toxin

Chlormequat chloride is a reproductive toxin that has adverse effects at extremely low levels in animal models. Its reproductive toxicity has been demonstrated in three mammalian species, and in both males and females. Torner et al (1999) found that, following low-level oral exposure of pregnant mice and their offspring to chlormequat chloride, the sperm of the male offspring achieved far lower fertilization and oocyte cleavage rates than sperm of untreated mice in *in vitro* fertilization tests. These effects were observed whether the chlormequat source was treated wheat, untreated wheat mixed with chlormequat, or chlormequat in drinking water, with doses on the order of 0.024 mg/kg/day (Sorensen and Danielsen 2006). Torner and colleagues conclude that chlormequat disrupted the sperm maturation process in the epididymis.

In a pig experiment, sows were fed chlormequat-treated wheat from 21 days of age until 30 days after their first litter had been weaned, with a dose on the order of 0.0023 mg/kg/day. Within the 30-day post-weaning period, all 22 of the control sows showed estrous and were mated, while 7 of 21 treatment sows did not show estrous and remained unmated. It was determined that most of the latter sows were cycling, and that it was thus only behavioral estrous that had been compromised (silent estrous), a condition that is associated with hormonal (estradiol) disruption (Danielsen et al. 1989 [in Danish], described in Sorensen and Danielsen 2006).

Xiagedeer et al. (2020) administered 5 mg/kg/day chlormequat chloride via oral gavage to pregnant rats during 11 or 20 days of gestation, and examined the effects in some maternal animals (sacrificed for examination on GD11) and the offspring of others, delivered after 20 days of gestation, on postnatal day 7. They found that chlormequat increased levels of growth hormone (GH) and GH-releasing hormone in maternal animals, and induced increased head length, decreased body fat percentage, hypoglycemia, hyperlipidemia and hyperproteinemia in the pups.

If one were to apply the standard 100x safety factor to the doses that caused harm in the first two studies described above, the resulting chronic reference doses would be at least 0.00024 mg/kg/day (mouse study) and 0.000023 mg/kg/day (pig study); with application of a 1000x safety factor to the rat study (an additional 10X factor for greater susceptibility of young

[25] 21 U.S.C. § 346a(b)(2)(A)(i).
[26] 21 U.S.C. § 346a(b)(2)(A)(ii).
[27] *Natural Res. Def. Council v. Whitman*, No. C 99-03701-WHA, 2001 WL 1221774 (N.D. Cal. Nov. 7, 2001).

vs. adult animal), the cRfD would be 0.005 mg/kg/day. Because all three cases involve points of departure that are LOAEL's rather than NOAEL's, the reference doses derived from them should be lower still. All of these are considerably below EPA's chronic reference dose of 0.05 mg/kg/day, which EPA based purely on registrant studies.

A review of chlormequat studies submitted to European pesticide regulators also reveals a host of adverse reproductive and developmental effects that include prenatal death, changes in male and female reproductive organs, reduced semen quality, impaired fertility of males and females, and anti-androgenic mode of action (Nielsen et al. 2012).

Despite this substantial evidence of reproductive impacts, and the strong implication of hormone disruption in at least one of these studies, EPA has yet to screen chlormequat chloride for its endocrine disruption potential.

Chlormequat chloride requires further testing for neurotoxicity

The other major category of harm, observed in registrant animal studies, is neurotoxicity, including ataxia, salivation, decreased body temperature and decreased motor activity) (EPA 3/16/21, p. 14), as well as modulation of cholinergic transmission, and agonistic action at the nicotinic acetylcholine and muscarinic acetylcholine receptors (Nielsen et al. 2012). Despite this evidence, EPA waived an otherwise required, subchronic (90-day) neurotoxicity study, not to mention failing to collect a developmental neurotoxicity study. EPA should require both before even considering the new use applications or associated tolerances.

High exposure levels by virtue of chlormequat's persistence and frequent detection in foods

Chlormequat chloride is one of the most frequently detected pesticide residues in European countries where it is used. In Denmark, chlormequat was detected in 87% and 83% of cereals tested in 1997 and 1998 (Granby and Vahl 2001), while 44 of 48 samples of wheat produced in the UK in 2002 contained chlormequat residues (Spink et al. 2004). In the European Union as a whole, chlormequat was by far the most frequently quantified pesticide in wheat in 2015, with 49% percent of samples testing positive, while in 2016, the EU detected chlormequat residues in 34% of rye samples (EFSA 2017, EFSA 2018).

Chlormequat chloride is extremely persistent. It is stable to hydrolysis and photolysis in water, and is not expected to degrade on the surface of sprayed leaves (EPA 3/26/21). Thus, it is not surprising that it turns up frequently not only in raw cereal commodities, but also in processed cereal products. In the EU, chlormequat was by far the most frequently detected pesticide in wheat flour, with 48% of samples testing positive in 2014 (EFSA 2016). In the UK, an astounding 88% (125 of 142) of bread and related bakery goods tested positive for chlormequat in the third quarter of 2018.[28]

With this ubiquitous presence in staple wheat-based foods, it is not unexpected that chlormequat shows up in biomonitoring. In fact, every single one of roughly 1,000 urine samples collected from Swedish adolescents over an 18-year period turned up positive for

[28] See results for Bread at https://data.gov.uk/dataset/5d5028ef-9918-4ab7-8755-81f3ad06f308/pesticide-residues-in-food.

chlormequat chloride: in 2000, 2004, 2009, 2013 and 2017, with roughly 200 samples each year (Noren et al. 2020, Table 3).

We know of no comparable test results – from residue tests on food, or biomonitoring – in the U.S. Neither USDA's Pesticide Data Program nor NIH's NHANES includes chlormequat among the compounds it tests for. At present, exposure would be limited mainly to imported grains, mostly from Canada. Undoubtedly, approval of the new uses and associated tolerances would lead to a massive increase in exposure to this toxic compound.

EPA's estimates of exposure far exceed the reproductive harm thresholds suggested above based on independent studies, by up to several orders of magnitude.

In this respect, it should be noted that that the European Union finds potential short-term consumer risks from exposure to some food items bearing residues of chlormequat (EFSA 2017, p. 83). Even in the U.S., chlormequat chloride is regarded as an "extremely hazardous substance." See 40 C.F.R. § 355.

It is clear that the proposed new uses and tolerances would lead to unsafe exposures to this highly toxic compound, and must not be granted.

Tolerance creep

CFS opposes the new use registrations, and establishment of any domestic tolerances for chlormequat, as the risks to human health of exposure far exceed any minor agronomic benefits. However, even if one were to consider some tolerances justified, those proposed by Taminco are far higher than are "needed" to accommodate the intended use of chlormequat to strength stalks of the pertinent grain crops: wheat, barley, oats and triticale.

The proposed tolerance for wheat of 5 ppm far exceeds past and current maximum residue levels (MRL's) established by other countries and Codex: just 1 ppm in Canada, a major wheat-producing nation, and a 2 ppm Codex MRL (EPA 3/16/21, Appendix A.5). The disparity for barley is even greater. Canada's MRL of 0.1 ppm and the 2 ppm Codex MRL for barley are 80-fold and 4-fold, respectively, below the Taminco-proposed tolerance of 8 ppm (Ibid). Most unacceptable is the proposal for a 40 ppm tolerance in or on oats. The Codex MRL is just 4 ppm, one-tenth that value, while the UK not long ago and perhaps today had/has a nearly equivalent MRL of 5 ppm (Spink et al. 2004).

High tolerances encourage bad agricultural practice and increase chlormequat exposure

Chlormequat residue testing carried out at three sites in the UK during the 2002-03 growing season revealed widespread contamination of wheat, barley and oats, but at levels substantially below then-prevailing tolerances, and even farther below the vastly inflated tolerances proposed by Taminco (Spink et al. 2004).

Two key factors driving high residue levels are application rate and timing (Ibid). As one would expect, higher rates lead to higher residues. The timing of application is even more important.

Spink et al. (2004) found that chlormequat residue levels in wheat, oats and barley grain increased sharply as the time of application advanced to later growth stages. Teittinen (1975) found vastly increased chlormequat residues in wheat when 2.5 kg/ha was applied 65 days before harvest (3.2 mg/kg) vs. 98 days before harvest (0.16 mg/kg). Likewise with application

of 0.69 or 1.38 kg/ha in oats, chlormequat residues increased from 0.23-0.33 mg/kg when applied at growth stages GS31/32 to 1.68-2.0 mg/kg when applied at GS45 (Gans et al. 2000, Tables 2 and 3).

While applications of chlormequat to grains were limited to GS31/32 in the past (Spink et al. 2004), EPA has approved experimental use permits in which applications are made as late as GS39 (EPA 3/16/21, Table 3.3, p. 11). Exposure to chlormequat could be considerably reduced if applications were restricted to earlier growth stages. Spink et al. (2004) found that changing the application timing from GS31 to an earlier growth stage – late tillering – dramatically reduced chlormequat residues without impacting performance. The same authors also found no benefit of applying chlormequat to barley.

These findings suggest that the ultra-high tolerances proposed by Taminco would encourage growers to make applications of chlormequat at far later growth stages than is recommended by agronomists, dramatically increasing exposure to this reproductive toxin. EPA should take note that approving ultra-high tolerances actively encourages off-label uses. It would be as if the National Highway Safety Administration were to post signs urging motorists to "slow down to save lives," while simultaneously increasing the highway speed limit to 150 mph. In like manner, label restrictions (e.g. do not apply after GS31/32) that are practically speaking unenforceable in the field (like "slow down" signs) will mean little or nothing if tolerance levels (which are subject to some degree of enforcement) are set high enough (like the speed limit) to ensure practically no chance of a tolerance violation (speeding ticket), even when the application is made far later in the crop's growth stage (the car is driven much faster) than is permitted by the label (compatible with the "slow down" signs).

Co-exposure aggravates adverse effects

The increased exposure to residues of this reproductive toxin that would ensue from granting the proposed tolerances would occur against a backdrop of exposure to a multitude of other such toxins, particularly other anti-androgens. Low-level co-exposures to multiple chemicals frequently have additive effects on common target tissues, a result which EPA scientists have found sometimes holds true even if components of the mixture have dissimilar mechanisms of toxicity (e.g. Rider et al. 2010). This means that safety thresholds established for individual substances may well not be protective in the real world of co-exposure to multiple chemicals (Kortenkamp et al. 2007, Nordkap et al. 2012).

This evidence is particularly strong for anti-androgenic compounds. Numerous animal studies show that *in utero* exposures to mixtures often have additive and occasionally synergistic adverse effects on a range of male reproductive endpoints, even when components of the mixture are administered at levels at or well below the individual NOAELs (Christiansen et al. 2009, Rider et al. 2010). As would be predicted from the dose addition principle, EPA research scientists found that the doses of individual chemicals needed to adversely affect male reproductive tract development decrease with increasing number of anti-androgens in the mixture (Conley et al 2018).

Sperm counts and quality have been declining for decades, with an over 50% reduction in sperm counts in men in developed countries from 1973 to 2011 (Levine et al. 2017).

Scientists attribute this decline in large part to increasing exposure to environmental chemicals, including pesticides (Martenies and Perry 2013, Gore et al. 2015, Chiu et al. 2015). The last thing we need is still another reproductive toxin in our environment and in our food.

ECOLOGICAL RISKS

It is difficult to judge the ecological impacts of the proposed new uses of chlormequat chloride – which as noted above could reach 40 million lbs sprayed on 40 million acres or more each year – based on an EPA ecological assessment geared to the impacts of spraying mostly greenhouse ornamentals with roughly 1,000 lbs/year total (see above). That assessment – conducted for Registration Review entirely without regard to the new uses at issue here (EPA 3/26/21) – is of only limited value for application to grain crops. For instance, EPA concedes that it eased up on data requirements at the outset of Registration Review in view of the "limited outdoor use patterns" associated with ornamentals-only use (EPA 3/26/21, pp. 11-13). That additional data might be needed here. Likewise, the assumption that spray drift is not an issue for bees because chlormequat is applied only with handheld equipment obviously does not apply here (Ibid, pp. 43-45). In the proposed interim registration review decision as well, EPA dismisses all risks of concern primarily because "the opportunity for chronic exposure from this use profile **may be limited for currently registered products"** (EPA 2021, pp. 10-11). Clearly, the proposed new grain uses are an entirely different ball of wax. Even so, some analysis is possible.

First, chlormequat chloride is extremely persistent. It essentially does not break down via hydrolysis or photolysis in water; it has an aerobic half-life of 6 to 9 months in U.S. soils, indicating slow microbial degradation; and is even more persistent in aquatic systems, with lab-based half-lives of 2 months to over 1 year in aerobic, and over 1 year to multiple years in anaerobic, conditions (EPA 3/26/21). That is, chlormequat persists and may build up in soils and water, and is essentially stable in aquatic sediments, where it will certainly build up over years of use.

Based on new metabolism studies with more exhaustive extraction of bound residues, and new policy to exclude unextracted residues from the "residues of concern" category, EPA seems to have gotten over its prior concern about chlormequat's persistence (EPA 3/26/21, p. 16). However, the entire issue of xenobiotics binding to organic matter as a solution to pollution is controversial, to say the least. In reviewing the problem, Barraclough et al. (2005) are concerned that turnover of soil organic matter could release xenobiotics that were originally safely bound, creating a toxic release problem for the future, particularly in the real world where hundreds to thousands of xenobiotics enter the soil and bind (at least temporarily) to it.

Birds and Mammals

EPA found both acute and chronic risks of concerns to herbivorous mammals and birds from chlormequat use on ornamentals, based on their consumption of chlormequat residues on grasses and other plants. The risk quotients at the higher end of the ranges are attributable to modeling of the calculated per-acre equivalent, spot-treatment application rate – 8.24 lbs/acre – used in shadehouses, and to modeling that employs the maximum single application rate of 3.7 lbs/acre. However, risks persist even when the application rate is 1.57 lbs/acre (EPA 3/26/21, p. 42), which would be relevant to a grain crop situation involving applications of 1 to 1.5 lbs/acre, as suggested by EPA's experimental use permit parameters (EPA 3/16/21, p. 11). A key factor here too is chlormequat's persistence. With little or no breakdown on plant surfaces (EPA 3/26/21, p. 37), the risks to herbivorous mammals and birds would persist longer than with pesticides that degrade more quickly.

This risk description, it should be emphasized, is based on EPA's analysis and endpoints derived from registrant studies. Clearly, if one considers chlormequat's impairment of reproduction in multiple mammalian species at very low doses (see above), risks are amplified by several orders of magnitude.

Terrestrial Invertebrates

Chlormequat also poses a clear threat to bees and other terrestrial invertebrates. EPA found chronic risks to adult honeybees of 4.1, based on application rate of 8.24 lbs/acre, and a 41% increase in mortality at the LOAEL. However, it should be noted that chronic risks to adult bees persist (RQ = 1.9) even with a maximum single application rate of 3.7 lbs/acre.

Still more concerning is the chronic risk to worker honeybee larvae (risk quotient = 45), based on an application rate of 8.24 lbs/acre, with risks to drone larvae even higher, RQ = 48 (Ibid., p. 72). The risk persists (RQ = 20) when one assumes 3.7 lbs/acre is applied, and would still be extremely high with an application rate more likely for cereal uses of 1.5 lbs/acre (RQ = 8). The adverse effect was a 15% reduction in adult emergence, a serious reproductive impact that would easily have colony-survival impacts in terms of reducing colony numbers over time. Two properties of chlormequat are pertinent here: its persistence, and its systemic nature. Together, these properties suggest it will very likely be translocated to pollen and nectar, just as it moves to grain, and persist there for collection by pollinators, as well as in the hive itself.

While EPA does not discuss any studies related to this, chlormequat has been shown to contaminate honeybees and their hives. In fact, of 23 pesticides measured by Erban et al. (2017) in dying honeybees and comb pollen of a honeybee hive that exhibited signs of poisoning in the Czech Republic, chlormequat was by far the most frequently detected, and at the highest levels.

With chlormequat's persistence in soil, ground-dwelling bees may be at even higher risk than honeybees, and appropriate studies are urgently needed to assess this potential risk as well.

Soil Organisms

Chlormequat may also have a deleterious impact on a multitude of soil organisms, from microscopic to macroscopic, and the failure to evaluate pesticidal impacts on soil life is a long-standing and gaping hole in EPA's risk assessment framework (Gunstone et al. 2021). EPA should fully assess chlormequat's potential adverse effects on a representative range of soil organisms (CBD-FoE 2021).

Scope of Use and Impacts

With the potential for tens of millions of pounds of chlormequat to be applied to an equivalent number of acres across the country, it is clear that the ecological risk assessment for registration review, which was geared to minor ornamental use, with only extremely limited use outdoors on containerized plants in shadehouses, cannot hope to do justice to the new uses on widely planted grain crops that Taminco has proposed. Center for Food Safety urges EPA to initiate a full public participation process for these new uses, and re-do the human health and ecological assessments to account for them, prior to releasing any final interim or final registration review decision.

Threatened and Endangered Species

EPA has not completed an assessment of chlormequat for its impact on threatened and endangered species. EPA must comply with its duties under Section 7 of the ESA prior to registering chlormequat for new uses, as this action may affect species listed as threatened or endangered under the ESA. Because imperiled species listed under the ESA are highly susceptive to additional threats, it is clear that listed species would be at increased risk from an approval. EPA should also refrain from issuing any final interim or final registration review decision prior to a full threatened and endangered species assessment.

Bill Freese, Scientific Director
Center for Food Safety

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