



November 28th, 2012

Electronic Mail

To: Thomas Carpenter
Designated Federal Officer
Science Advisory Board –Perchlorate Advisory Panel

From: Hank Giclas
Senior Vice President
Science, Technology & Strategic Planning

Re: US EPA's Proposed Use of Life Stage Specific Values to Derive an MCLG for Perchlorate in Drinking Water

Western Growers is a non profit trade association that represents producers and handlers of fresh fruits, nuts and vegetables in California and Arizona. Our approximately 1000 grower, shipper, processor members collectively produce and sell more than half of the U.S. fruits and vegetables and almost a third of the nations organic produce.

Historically, our organization has been concerned with the regulation of perchlorate and its implications for the produce industry. We appreciate the opportunity to provide comments as the Science Advisory Panel on perchlorate considers US EPA's proposal to change the manner in which toxicological risk assessments have traditionally been conducted by the Agency. Western Growers urges panelists to carefully consider this precedent setting action as we believe it will affect the future regulation of countless chemicals.

The news of this prospective change has not been widely shared nor, as yet, fully understood. It is being undertaken in the context of the Agency's calculation of a proposed Maximum Contaminant Level Goal (MCLG) for one chemical, perchlorate. In turn, the regulatory process for perchlorate itself is failing to meet statutory requirements. The implications are widespread and significant.

The undersigned agriculture organizations object to any agency making fundamental policy changes in this manner. We strongly urge US EPA to subject its proposed risk assessment policy changes to a separate, open and transparent review process so that all potentially affected stakeholders, not just those with an interest in perchlorate regulation, have an opportunity to engage in the policy-setting process.

We have a number of specific concerns about the Agency's perchlorate rulemaking process, including:

- The agency’s decision not to vet changes through appropriate administrative review or provide opportunity for public comment.
- The acknowledgment in the SAB report that the current standard recommended by the National Academy of Science in 2005, appears to be working (no reported health effects in the literature to warrant a lower standard); and
- The SAB policy recommendation that EPA stop regulating based upon actual data and instead start regulating based upon theoretical assumptions. The basis for this fundamental switch is not because there is a problem with the standard recommended by the National Academy of Science, but because the SAB thought the switch was a "reasonable inference".

Each of these concerns notwithstanding, we are writing today with a focused comment on the implications of proposed changes to the MCLG calculations to reflect “life stage” differences.

These changes will result in redundant application of assumptions to protect potentially sensitive populations and would incorporate body weight and drinking water intake parameters that are inconsistent with the scientific database. For perchlorate, these changes could result in an enforceable regulatory standard that is overly conservative and not based on solid scientific judgment. The net result would be a decrease in the perchlorate MCLG from 15 ppb to 1 or 2 ppb, without appropriate scientific justification for this change.

Applying life stage-specific values to calculate an MCLG represents a deviation from standard US EPA risk assessment practice. If these changes are used by US EPA, the same parameters could be applied to the calculation of MCLGs and MCLs for other chemicals, including other agricultural chemicals such as herbicides, insecticides, and soil enhancing chemicals. This departure from established methodology in favor of an unscientific, overly cautious and redundant method deserves far more attention and critical review. This potential precedent setting approach should be widely communicated to all potential stakeholders for their review and comment prior to any further consideration.

1.0 BACKGROUND

In US EPA’s (2009) *Drinking Water: Perchlorate Supplemental Request for Comments*, US EPA proposed to calculate a Health Reference Level (HRL) for perchlorate using drinking water intake rates and body weights for specific life stages. Subsequently, US EPA has applied this same methodology in its White Paper, *Life Stage Considerations and Interpretation of Recent Epidemiological Evidence to Develop a Maximum Contaminant Level Goal for Perchlorate*, to calculate a proposed Maximum Contaminant Level Goal (MCLG) for perchlorate (US EPA, 2012a).

2.0 CALCULATION OF A PROPOSED MCLG USING “LIFE STAGE CONSIDERATIONS”

Traditionally, US EPA has calculated MCLGs from oral reference doses (RfDs) by assuming consumption of 2 L/day of drinking water by a 70-kg adult. The standard equation for calculating an MCLG is as follows (US EPA, 1999):

$$MCLG \left(\frac{mg}{L} \right) = \frac{RfD \left(\frac{mg}{kg-d} \right) * BW (kg)}{DWI \left(\frac{L}{d} \right) * RSC}$$

Where, for perchlorate,

RfD = Reference dose, 0.0007 mg/kg-d

BW = Body weight for an adult, 70 kg

DWI = Drinking water intake rate, 2 L/d

RSC = Relative source contribution for drinking water, 0.62 (Huber et al., 2011)

This calculation would result in an MCLG of 0.015 ppm or 15 ppb.

To reflect “life stage” differences, US EPA has proposed replacing the standard BW and DWI with values that are specific for certain age groups. In the White Paper, US EPA suggests the calculation of life stage-specific MCLGs for perchlorate as follows:

Table 1: MCLG Derivation for Perchlorate.

Sensitive Life Stage	RfD ¹ (µg/Kg BW/Day)	Mean BW (kg) ²	DWI, 90 th Percentile (L/day) ²	RSC ³	MCLG (µg/L) ⁴
Females 13-49 years	0.7	66	2.11	0.80	18
Pregnant women for gestational week (GW) 40 fetuses	0.7	78	2.57	0.72	15
Breast-fed infants, 7 days	0.7	74	2.96	0.72	13
Breast-fed infants, 30 days	0.7	73	2.96	0.72	12
Breast-fed infants, 60 days	0.7	72	2.96	0.72	12
Bottle fed infants, 7 days	0.7	3.6	0.84	0.59	2
Bottle fed infants, 30 days	0.7	4.2	0.98	0.59	2
Bottle fed infants, 60 days	0.7	5.0	1.14	0.59	2
Infants, 6-12 months	0.7	9.2	1.03	0.59	4
Children 1 to <2 years	0.7	11.4	0.64	0.44	6

¹RfD was derived by NRC in 2005 based on Greer *et al.* (2002) and later adopted by EPA Integrated Risk Information System (U.S. EPA, 2005a).

²The mean body weight and the 90th percentile drinking water intake values for different life stages were based on Exposure Factors Handbook (U.S. EPA, 2011b) and from ORD’s PBPK Modeling effort (U.S. EPA, 2009c).

³The RSC values for various life stages were adopted from the Table 5 and 6 of the U.S. EPA report (U.S. EPA, 2008). The RSC for pregnant women and females of reproductive age 13-49 years were calculated based on the data from Huber *et al.* (2011).

⁴MCLG (in µg/L) was calculated based on the formula $MCLG (\mu g/L) = [RfD (\mu g/kg \text{ bw/day}) \times BW (kg) / DWI] \times RSC$.

Application of life stage-specific BWs and DWIs in the perchlorate calculation is redundant.

The RfD for perchlorate is already protective of sensitive population groups. The RfD (0.0007 mg/kg/day) is based on a No Observed Effect Level (NOEL) reported in Greer et al. (2002) with an Uncertainty Factor (UF) of 10 to account for populations that are more sensitive (e.g., fetuses, infants) than the study population (adults). This NOEL point of departure reflects the dose of

perchlorate in drinking water that, when delivered to human volunteers, resulted in no change over background for the parameter evaluated — iodide uptake inhibition (IUI) into the thyroid. IUI is a non-adverse, adaptive effect that precedes other effects (e.g., thyroid hormone changes) that can occur at much higher levels of exposure. Basing the perchlorate RfD on a NOEL is a conservative, health protective approach, as opposed to using a No Observed Adverse Effect Level (NOAEL) or a Lowest Observed Adverse Effect Level (LOAEL), as is typically done when developing RfDs (US EPA, 1993).

US EPA's White Paper suggests that consideration of life stages is necessary since neonates are more susceptible to effects of perchlorate exposure. Even if one were to accept this premise in the absence of supporting evidence, what the life-stage specific analysis actually shows is that the most sensitive sub-populations are fully protected by the UF of 10 that was incorporated into the RfD. The life-stage analysis shows that the most sensitive sub-populations are about 8 to 9 times more sensitive to perchlorate exposure than an adult, based on the body-weight and water ingestion values used by US EPA. What this means is that the life-stage analysis demonstrates that applying a UF of 10 to the NOEL reported in Greer does in fact protect the most sensitive sub-populations.

Limitations in the data supporting USEPA's life stage analysis.

The BW and DWI values applied in the life stage-specific approach are based on a report by Kahn and Stralka (2009). The BW and DWI values reported by Kahn and Stralka are themselves overly conservative. For example, the body weights presented by Kahn and Stralka (2009) are lower than those reported in the 1996-2000 National Health and Nutrition Examination Survey (NHANES), as presented in US EPA's *Child-Specific Exposure Factors Handbook* (US EPA, 2008). NHANES is designed to assess the health and nutritional status of adults and children in the United States. As such, the BW values may not be representative of the general population. For example, for one month olds, the Kahn and Stralka (2009) mean BW is 20% lower than the NHANES 1996-2000 mean for the same group.

The DWI values presented by Kahn and Stralka (2008) are 90th percentile DWIs from a study in which participants recalled their own (or their infant's) consumption over two non-consecutive days; no direct measurements were taken. Recall studies are subject to error (termed recall bias) from lapses in memory about the amounts consumed (*i.e.*, what, when, and how much did I eat or drink?). If, for example, one or two individuals in the study overestimated intake, the data would be skewed and the statistical estimation of the 90th percentile water consumption values would be overestimated.

3.0 IMPLICATIONS OF THE PERCHLORATE MCLG CALCULATION

As established by US EPA, an MCLG is the level of a contaminant in drinking water below which there is no known or expected risk to health; an MCLG allows for a margin of safety and is a non-enforceable public health goal. MCLGs are typically used as the basis for Maximum Contaminant Levels (MCLs), which are enforceable drinking water standards and are set as close to MCLGs as feasible, using the best available treatment technology and taking cost into consideration (U.S. EPA, 2012a). US EPA's proposed changes in the calculation of the perchlorate MCLG will likely decrease the final perchlorate MCL. If the life stage-specific analysis is used by US EPA, the same analysis could be applied to any other chemical where a MCL has been or will be derived, including other agricultural chemicals such as herbicides,

insecticides, and soil enhancing chemicals. To this end, US EPA must be transparent in its derivation of acceptable exposure levels to ensure that these levels are both health protective and science-based.

Historically, the safety of agricultural commodities, and more specifically, fruits, vegetables and dairy products has been called into question by activist organizations aggressively pursuing the cleanup of perchlorate in drinking water in California and elsewhere. The resulting food scares confuse consumers and discourage the consumption of nutritious food important to the diets of children and adults alike. As representatives of agricultural producers we anticipate that similar scares may manifest, with a significant and unfounded reduction in the perchlorate MCLG and MCL.

In addition, water prices for agricultural users in areas where a lower MCL necessitates investment for cleanup, will place producers at a distinct competitive disadvantage. With the potential for these negative financial impacts and the potential for this methodology to set the stage, through precedent, for a variety of similar evaluations with equally or more significant negative consequences for agriculture, we strongly encourage the SAB to reject this methodology.

If an MCLG for perchlorate is to be developed using USEPA's proposed life stage methodology, which disregards the weight of scientific evidence, relies on questionable studies, and applies redundant uncertainty factors to account for sensitive populations, we strongly recommend that US EPA initiate a separate and broader review of its proposed risk assessment policy changes. This process should include a proactive effort to solicit commentary from all stakeholders that may be impacted by the proposed shift in methods for perchlorate and other compounds.

In conclusion, Western Growers is opposed to the use of this methodology for the derivation of an MCLG for perchlorate and for related compounds. If the panel moves forward, however, to endorse or recommend this methodology we assert that the implications extend well beyond this single chemistry and such a shift in policy should be much more broadly communicated, vetted and transparent in nature. The SAB and the USEPA must step back and proactively extend and communicate the proposed shift in policy so that the potential impacts are more fully understood and vetted within the industrial, academic and public communities.

If you have questions about Western Growers or our comments on this matter please do not hesitate to contact me. Thank you for the opportunity to provide these comments and for your consideration.

Respectfully submitted,

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