



## MEMORANDUM

On May 4, 2007, Governor Tim Pawlenty signed, and deposited with the Secretary of State, Chapter 37 of the 2007 Laws of Minnesota. In addition to other requirements, this legislation directed the Commissioner of Health to:

develop and adopt by rule, pursuant to Minnesota Statutes, section 14.388, subdivision 1, clause (1), health risk limits, as defined in Minnesota Statutes, section 103H.005, subdivision 3, for perfluorooctanoic acid, and perfluorooctane sulfonate. The commissioner shall develop and adopt the health risk limits according to Minnesota Statutes, section 144.0751, and ensure that the health risk limits are based on currently available toxicity and exposure data.<sup>1</sup>

Chapter 37 was effective on the day following final enactment.<sup>2</sup>

The legislation has a number of noteworthy features that are relevant to the later legal review of the proposed rules. First, the state legislature's directive that "the commissioner shall develop and adopt by rule" health risk limits for perfluorooctanoic acid (PFOA), and perfluorooctane sulfonate (PFOS) "pursuant to Minnesota Statutes, section 14.388, subdivision 1, clause (1)," makes two points clear: the Legislature concluded that the ordinary rulemaking procedures of Chapter 14 are "unnecessary, impracticable, or contrary to the public interest," and that the sought-after health risk limits are needed to "address a serious and immediate threat to the public health, safety, or welfare."<sup>3</sup> Minn. Stat. § 14.388 provides an abbreviated rulemaking procedure where an agency can show good cause for use of that provision. In this instance, however, the Legislature has determined (and specified in Chapter 37) that good cause is present.<sup>4</sup>

Second, section 14.388 provides that the agency must satisfy the requirements of Minn. Stat. § 14.386(a)(1)-(4) in order to adopt a rule. Under those provisions the Revisor of Statutes must approve the form of the rule, the agency head must adopt the rule, the Office of Administrative Hearings must approve the rule as to its legality and the rule must be published in the State Register.

The legality determination by OAH is governed by Minn. Rule pt. 1400.2400, subp. 3, which states that in reviewing a filing the judge must decide

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<sup>1</sup> See, 2007 Laws of Minnesota, Chapter 37, Section 1.

<sup>2</sup> *Id.*

<sup>3</sup> See, Minn. Stat. § 14.388 (1)(1) (2007).

<sup>4</sup> Compare, e.g., *In the Matter of the Adoption of Rules Governing Voter Registration, Minnesota Rules, Chapters 8200 and 8210*, OAH Docket No. 70-3500-16046-1 (2004) (<http://www.oah.state.mn.us/aljBase/350016046.or.htm>).

whether the rule meets the standards of part 1400.2100, Items A and D to G. Those standards of review provide as follows:

A rule must be disapproved by the judge or chief judge if the rule:

A. was not adopted in compliance with procedural requirements of this chapter, Minnesota Statutes, chapter 14, or other law or rule, unless the judge decides that the error must be disregarded under Minnesota Statutes, section 14.15, subdivision 5, or 14.36, subdivision 3, paragraph (d);

. . .

D. exceeds, conflicts with, does not comply with, or grants the agency discretion beyond what is allowed by its enabling statute or other applicable law;

E. is unconstitutional or illegal;

F. improperly delegates the agency's powers to another agency, person or group;

G. is not a "rule" as defined in Minnesota Statutes, section 14.02, subdivision 4, or by its own terms cannot have the force and effect of law. . . .

Minn. Stat. § 14.388, subd. 2 provides that interested parties have five business days after the date of the Notice of Adoption to submit comments to the Office of Administrative Hearings. The comment period ended on August 10, 2007 at 4:30 p.m. OAH received four timely-submitted comments regarding this rule.

Third, while the ordinary review of rules under the "good cause exemption," specifically excludes assessments of the reasonableness of the proposed rules,<sup>5</sup> in this instance the enabling legislation reintroduces some inquiry into the reasonableness of the Department's selections when issuing health risk limits. Chapter 37 requires that the adoption of health risk limits for PFOA and PFOS be made "according to Minnesota Statutes section 144.0751," and so as to "ensure that the health risk limits are based on currently available toxicity and exposure data."<sup>6</sup> Minn. Stat. § 144.0751 further provides that:

(a) Safe drinking water or air quality standards established or revised by the commissioner of health must:

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<sup>5</sup> Compare, Minn. R. 1400.2400 (3) (2005) with Minn. R. 1400.2100 (B) (2005).

<sup>6</sup> See, 2007 Laws of Minnesota, Chapter 37, Section 1.

(1) be based on scientifically acceptable, peer-reviewed information; and

(2) include a reasonable margin of safety to adequately protect the health of infants, children, and adults by taking into consideration risks to each of the following health outcomes: reproductive development and function, respiratory function, immunologic suppression or hypersensitization, development of the brain and nervous system, endocrine (hormonal) function, cancer, general infant and child development, and any other important health outcomes identified by the commissioner.

(b) For purposes of this section, "peer-reviewed" means a scientifically based review conducted by individuals with substantial knowledge and experience in toxicology, health risk assessment, or other related fields as determined by the commissioner.<sup>7</sup>

In this circumstance, therefore, in order to complete an assessment of whether the proposed health care limits "exceeds, conflicts with, does not comply with, or grants the agency discretion beyond what is allowed by its enabling statute or applicable law,"<sup>8</sup> some inquiry into the agency's choices of data, "margins of safety" and "peer-reviewed information" is needed.

When Chapter 37 and Minn. Stat. § 144.0751 are read together, three essential requirements are presented. The Commissioner is to develop health risk limits for PFOA and PFOS that:

- (1) reflects scientifically acceptable, peer-reviewed information;
- (2) includes a reasonable margin of safety to protect the health of infants, children and adults from health outcomes that are specified in statute and by the Commissioner; and
- (3) are based on currently available toxicity and exposure data.

Because the health risk limits developed by the Department meet each of these statutory standards, approval of the proposed rules is warranted.

At the core of the controversy over the proposed health risk limits, is a dispute over the integers that should be used in an important equation. The founding blocks of both the Department's assignment of health risk limits, and the sharp critiques of the commentators who timely responded to the proposed limits,

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<sup>7</sup> See, Minn. Stat. § 14.388 (1)(1) (2007).

<sup>8</sup> Compare, Minn. R. 1400.2100 (B) and (D) (2005) with Minn. R. 1400.2400 (3) (2005).

are the numerical values that should be used to complete the following calculation:

<p style="text-align: center;">Health Risk Limits (in micrograms per liter) =</p>	$\frac{\text{(Reference dose) (Weight of the subject)} \\ \text{(Relative source contribution) (1,000)}}{\text{(time weighted water intake in units of liters} \\ \text{per kilogram of human body weight per day)}}$
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The Department’s calculations for PFOA and PFOS revise and supplement the values stated in its earlier regulation “Health Risk Limits for Systemic Toxicants.”<sup>9</sup>

Minnesota Mining and Manufacturing (3M), the Minnesota Center for Environmental Advocacy and Dr. David Gray all urge different values to be placed into the Department’s health risk limit equation. Yet, the claim that another integer represents a better choice does not establish that the Department’s selections fail to provide “a reasonable margin of safety,” as those terms are used in Chapter 37. Particularly instructive in this regard, is the summary that Administrative Law Judge Bruce D. Campbell made on a similar question, nearly fifteen years ago. Judge Campbell observed:

The word “reasonable” is perhaps one of the most relative and generic terms used in the law and it is difficult to formulate an adequate or all-encompassing definition. The word “reasonable” has been defined in the law as “ordinary or usual”, “not immoderate or excessive”, “not capricious, arbitrary, or confiscatory.” When employed to describe the means which are used to achieve a legitimate end, it suggests not necessarily the best or only method but one fairly appropriate, at least under all circumstances. It has been said that conduct is reasonable if it is consistent with that of a prudent person in like circumstances. The word has also been held to be the equivalent of the words “adequate”, “moderate”, and “ordinary”.

“Reasonably”, when used as a qualifying adverb likewise has many shades of meaning, depending in a particular case on the context or attendant circumstances. It is defined as meaning in a “reasonable manner”, “consistently with reason”, “fairly”, “in moderate degree”, “measurably”, “moderately”, “tolerably”, “not extravagantly, excessively, or fully.”<sup>10</sup>

<sup>9</sup> Compare, Minn. R. 4717.7100 through 4717.7800 (2007) and Minn. Stat. § 103H.005 (3) (2006) with 3M’s Exhibits 2 and 3 (February 26, 2007 Memoranda of Helen Goeden).

<sup>10</sup> See, *In the Matter of the Application of Northern States Power Company for Reissuance of the Air Emission Permit for the Allen S. King Generating Plant*, OAH Docket No. 2-2200-7921-2 (1993) (citing 75 C.J.S. 635 and 75 C.J.S. 638 omitted) (<http://www.oah.state.mn.us/aljBase/22007921.93.htm>).

By any fair reading of the February 26, 2007 memoranda which underlie the Department's PFOA and PFOS health risk limits, the promulgated standards are "moderate" and "consistent with reason."

Moreover, in accordance with the statutory mandates, the proposed health risk limits: (1) reflect scientifically acceptable, peer-reviewed information;<sup>11</sup> (2) include a reasonable margin of safety to protect the health of infants, children and adults from specified health outcomes;<sup>12</sup> and (3) are based on currently available toxicity and exposure data.<sup>13</sup>

Lastly, if the commentators (or others) are not persuaded by the analyses that appear in the February 26, 2007 memoranda, and believe that other numerical values should represent the "reference dose,"<sup>14</sup> "relative source contribution"<sup>15</sup> or "intake values,"<sup>16</sup> their best remedy is to present these views directly to the Minnesota Legislature. Just as the Legislature directed the Commissioner of Health to render her best judgment on the question of health risk limits, and to work within specified parameters, the Legislature is at liberty to revise those directives or to substitute other health risk limits as it sees fit.

## CONCLUSION

Pursuant to Minnesota Statutes, sections 14.386 and 14.388, subdivision 1, clause 1, the amendments to Minnesota Rules, parts 4717.7200, 4717.7500, and 4717.7650 are approved as to legality.

With the approval of the adopted rules, our office has closed its file and will return the rule record to the Minnesota Department of Health. Our office will file four certified copies of the rules with the Secretary of State. The Department may publish a copy of the amendment in the State Register pursuant to Minn. Stat. § 14.386(a)(4). The amendments will be effective upon publication.

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<sup>11</sup> See, Attachment to 3M's Exhibit 2 at 2 through 7; Attachment to 3M's Ex. 3 at 2 through 7.

<sup>12</sup> See, Attachment to 3M's Ex. 2 at 1 through 3; Attachment to 3M's Ex. 3 at 1 through 3.

<sup>13</sup> See, Attachment to 3M's Ex. 2 at 1 through 7; Attachment to 3M's Ex. 3 at 1 through 7.

<sup>14</sup> See, Comments of 3M at 13 through 17; Comments of David Gray at 4.

<sup>15</sup> See, Comments of 3M at 12 and 13; Comments of D. Gray at 2.

<sup>16</sup> See, Comments of MCEA at 2; Comments of 3M at 11 and 12.