

## C O M M E N T

# A Troubling Precedent: Implementing the Precautionary Principle to Limit the Role of Science in European Decisionmaking

by Kevin Fast

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The precautionary principle is a deceptively appealing, but much debated, concept in the United States. As reflected in the common idioms, “an ounce of prevention is worth a pound of cure” or “it’s better to be safe than sorry,” proponents argue that the precautionary principle should be rigorously applied to ensure the safety of human activities that potentially impact public health or welfare *before* those activities commence.<sup>1</sup> Detractors argue, on the other hand, that the principle is potentially dangerous because it can be misused as a rationale to displace rigorous scientific analysis and, thereby, to support arbitrary government action.<sup>2</sup> Whatever the relative merit of these differing views in the United States, one place where the debate about the precautionary principle has effectively ended is in the European Union (EU). The EU has openly and explicitly adopted the precautionary principle as a foundation for all of its environmental regulatory activity. Any debate that remains concerning the precautionary principle in the EU relates solely to its implementation, not its application.

This Article addresses a recent judicial decision issued by the European Court of Justice (ECJ) that ought to be troubling to those who fear that the precautionary principle can be misused to limit the role of science in regulatory decisionmaking. The decision at issue is *Afton Chemical Limited v. Secretary of Transport*.<sup>3</sup> Although the decision specifically involves application of the precautionary principle to the setting of motor vehicle fuel specifications in the EU, the reach of the decision potentially extends to any decisions impacting human health or the environment.

The decision is troubling because it sanctions application of the precautionary principle to restrict use of products in Europe without even the most rudimentary scientific review, provided the restriction is “temporary” in nature, and the restriction is coupled with a directive for some sort of “future” scientific review. In this way, the decision potentially opens the floodgates for any number of “temporary” regulatory restrictions without adequate scientific justification and based purely on a “political” application of the precautionary principle.

The first section below provides a brief overview of the precautionary principle as a legal principle in the EU, as well as the EU Commission’s interpretation of the principle. The second section describes the decision in *Afton Chemical Limited*. The third section discusses the potential implications of the decision and provides some general thoughts on the precautionary principle and its potential application to the risks associated with the combustion of motor vehicle fuels, particularly gasoline.

## I. The Precautionary Principle in the EU

The EU Treaty in existence at the time *Afton Chemical Limited* commenced specifically refers to the precautionary principle in Article 174(2), as modified by the Maastricht Treaty in 1992: “Community policy on the environment shall aim for a high level of protection. . . . *It shall be based on the precautionary principle . . .*”<sup>4</sup> Precisely what is meant by the precautionary principle is unclear, however, because the EU Treaty does not define the term.

The EU Commission issued guidance in 2000 to provide a framework for incorporating the precautionary principle into regulatory decisions concerning human health

1. See, e.g., Thomas McGarity, *MTBE: A Precautionary Tale*, 28 HARV. L. REV. 281-342 (2004); Wingspread Statement on the Precautionary Principle (1998), available at <http://www.sehn.org/wing.html>.  
2. See, e.g., Cass Sunstein, *The Paralyzing Principle*, REGULATION 32-37 (Winter 2002-2003), available at <http://www.cato.org/pubs/regulation/regv25n4/v25n4-9>.  
3. Case No. C-343/09 (2010). A copy of the decision can be obtained from <http://eur-lex.europa.eu>.

4. Emphasis added. The more recent Treaty on the Functioning of the European Union contains the same language in Article 191(2).

and the environment.<sup>5</sup> The Commission's guidance identified three conditions that have to be satisfied for application of the precautionary principle:

- Potential negative effects must be identified<sup>6</sup>;
- There must be a scientific evaluation of those negative effects<sup>7</sup>; and
- The scientific evaluation must indicate the existence of uncertainty.<sup>8</sup>

Regarding the nature of the requisite "scientific evaluation," the Commission's guidance states: "An assessment of risk should be considered where feasible when deciding whether or not to invoke the precautionary principle."<sup>9</sup> Such an assessment, according to the Commission, "requires reliable scientific data and logical reasoning, leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact on the environment, or health of a given population including the extent of possible damage, persistency, reversibility and delayed effect."<sup>10</sup> When a comprehensive risk assessment is not possible, moreover, "all effort should be made to evaluate the available scientific information" and "[w]here possible, a report should be made which indicates the assessment of the existing knowledge and the available information, providing the views of the scientists on the reliability of the assessment as well as on the remaining uncertainties."<sup>11</sup>

Judicial decisions addressing the precautionary principle in Europe leading up to the decision in *Afton Chemical Limited* are generally consistent with the Commission's guidance. A good example is the decision in *European Commission v. Republic of France*, a decision issued shortly before the decision in *Afton Chemical Limited*. At issue in *European Commission* was national legislation that imposed an across-the-board, "pre-authorization" scheme for the use of processing aids in the preparation of foodstuffs. The national law in question prohibited the introduction, even temporarily, of "chemical products" during the preparation of goods and foodstuffs for human consumption "other than those the use of which is declared lawful . . . ." <sup>12</sup> The Commission challenged the national legislation as, among other things, an unwarranted obstacle to the free movement of goods in Europe.<sup>13</sup> France defended the restriction

arguing, among other things, that it was justified on health grounds based on the precautionary principle.<sup>14</sup>

The Court ultimately sided with the Commission. The Court agreed that "a Member State may base justification on the precautionary principle,"<sup>15</sup> observing:

Where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialize, the precautionary principle justifies the adoption of restrictive measures, provided they are non-discriminatory and objective.<sup>16</sup>

However, the Court determined that "a correct application of [the precautionary] principle presupposes that the Member State demonstrates the existence of the conditions . . . required for the [precautionary principle] to apply."<sup>17</sup> In the Court's words:

A correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health . . . and, secondly, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research.<sup>18</sup>

In the case before it, the Court concluded, "there is no demonstration of the existence of those conditions."<sup>19</sup> The only evidence proffered by France to support the national legislation was a "generalized presumption of a health risk," which the Court rejected as a basis for applying the precautionary principle.<sup>20</sup> As explained by the Court:

A decision to prohibit marketing, which indeed constitutes the most restrictive obstacle to trade in products lawfully manufactured and marketed in other Member States, can be adopted *only if the real risk alleged for public health appears sufficiently established on the basis of the latest scientific data available at the date of the adoption of such decision*. In such a context, the object of the risk assessment to be carried out by the Member State is to appraise the degree of probability of harmful effects on human health from the addition of certain nutrients to foodstuffs and the seriousness of those potential effects.<sup>21</sup>

The Court acknowledged that "the assessment which a Member State *is required to make* may reveal a high degree

5. Communication from the Commission on the Precautionary Principle, COM(2000) 1 (Feb. 2, 2000).

6. *Id.* Point 5.1.1.

7. *Id.* Point 5.1.2.

8. *Id.* Point 5.1.3.

9. *Id.* Point 5.1.2.

10. *Id.*

11. *Id.*

12. *European Commission v. Republic of France*, Case No. C-333/08 (Jan. 2010), ¶ 18.

13. *Id.* ¶ 46.

14. *Id.* ¶ 68.

15. *Id.* ¶ 96.

16. *Id.* ¶ 93.

17. *Id.* ¶ 96.

18. *Id.* ¶ 92.

19. *Id.* ¶ 97.

20. *Id.*

21. *Id.* ¶ 89 (emphasis added).

of scientific and practical uncertainty.”<sup>22</sup> The Court also acknowledged that when such uncertainty has been demonstrated by means of the required assessment, “a Member State may, under the precautionary principle, take protective measures without having to wait for the reality and the seriousness of those risks to be fully demonstrated.”<sup>23</sup> But where the requisite scientific assessment has not been completed, the Court concluded that “[i]t is not sufficient to base justification on potential risks” and the precautionary principle.<sup>24</sup>

In short, the EU has fully embraced the precautionary principle as a basis for ongoing efforts by its political institutions to protect public health and welfare. Not surprisingly, therefore, European Court decisions and Commission guidance also reflect the importance of the precautionary principle, and both have worked hand-in-hand to help define the conditions necessary to support “precautionary” regulation. Prior to the decision in *Afton Chemical Limited*, one such condition was completion of a scientific assessment. With the decision in *Afton Chemical Limited*, however, the continuing need for science to support precautionary action in Europe has been cast very much in doubt.

## II. *Afton Chemical Limited*

The decision in *Afton Chemical Limited* involves the gasoline fuel additive known as mmt®.<sup>25</sup> mmt® is a manganese-based gasoline fuel additive that increases the octane of gasoline. Automakers have long opposed use of mmt® in gasoline, and the producer of mmt® has long defended the merits of the additive. Afton Chemical Limited (Afton) is one of the producers of mmt®.

### A. *Background to the Decision*

Directive 98/70/EC introduced the current European regime for petrol (or gasoline, as it is known in North America) and diesel fuel quality. In its original form, Directive 98/70 contained no reference to metallic additives (other than a restriction on the use of lead additives in petrol). Directive 98/70 was amended by Directive 2003/17/EC on March 3, 2003.<sup>26</sup> This amendment required the Commission to review, among other things, the impact of metallic additives on the performance of new pollution abatement technologies.

In accordance with the provisions of Directive 2003/17, the Commission and the Joint Research Centre (JRC) undertook a consultation process with stakeholders and interested parties in preparation for a new proposal

amending Directive 98/70.<sup>27</sup> Part of the JRC consultation process concerned metallic additives and efforts by the JRC to develop a “test protocol” to assess the impact of metallic additives on the performance of vehicle emission control systems.

On January 31, 2007, the Commission sent a proposed new directive amending Directive 98/70 to the Parliament and the Council. The principal focus of the amendments was the introduction of measures to reduce greenhouse gas emissions from motor vehicles, including the introduction of ethanol and other biofuels.<sup>28</sup> Regarding metallic additives, the Commission proposed to continue development of a test protocol to determine the impact of such additives on vehicle performance.<sup>29</sup> The supporting materials accompanying the Commission’s proposal indicate that the Commission considered the effect of metallic additives on vehicles and emissions to be “unclear,” noting “there has been no comprehensive assessment of the health impacts of the use of the additives.”<sup>30</sup> The Commission proposed to continue development of a test protocol “to improve understanding” and because “[n]o sufficiently compelling evidence has been provided for either a generalized ban on metallic additives, or a ban of a specific product.”<sup>31</sup> The Commission recognized, moreover, that any restriction on the use of metallic additives would have to be based on further assessments of the relevant scientific and technical data.<sup>32</sup>

The lead committee of Parliament in charge of amending Directive 98/70 took a different view, however, at least in the case of mmt®. On July 19, 2007, the Environment Committee proposed the following amendment to the Commission’s proposal:

Use of the metallic additive MMT in fuel shall be prohibited from 1 January 2010 onwards. The Commission shall develop a suitable test methodology concerning the use of metallic additives in fuel other than MMT.<sup>33</sup>

22. *Id.* ¶ 91 (emphasis added).

23. *Id.*

24. *Id.* ¶ 95.

25. mmt® is a registered trademark owned by Afton Chemical Corporation.

26. Directive 2003/17/EC of the European Parliament and Council of 3 March 2003 amending Directive 98/70/EC relating to the quality of petrol and diesel fuels. 2003 O.J. (L 76) 22.3.03, 10-19.

27. The JRC provides independent scientific and technical advice to the Commission and Member States in support of EU policies. See <http://ec.europa.eu/dgs/jrc>.

28. Proposal for a Directive of the European Parliament and of the Council amending Directive 98/70/EC, as regards the specification of petrol, diesel, and gas-oil and the introduction of a mechanism to monitor and reduce greenhouse gas emissions from the use of road transport fuels and amending Council Directive 1999/32/EC, as regards the specification of fuel used by inland waterway vessels and repealing Directive 93/12/EEC. COM (2007)18 final [hereafter Commission’s Proposal].

29. *Id.* (proposed Article 8a).

30. Explanatory Memorandum to the Commission’s Proposal, 5-6; Impact Assessment for a Proposal for a Directive of the European Parliament and of the Council Modifying Directive 98/70 Relating to the Quality of Petrol and Diesel Fuels, SEC(2007)55, 68 [hereafter Impact Assessment].

31. Impact Assessment, *supra* note 30, at 71 and 73.

32. *Id.* at 71 (“Under the TBT Agreement WTO Members have the right to enact technical regulations to pursue certain legitimate objectives, protection of environment among them. Such regulations, however, cannot be more trade-restrictive than necessary to fulfil the objective they pursue taking into account the risk non-fulfilment would create. The latter would be assessed by referring to a number of relevant elements such as available scientific and technical information.”).

33. Draft Report, Committee on the Environment, Public Health, and Food Safety, 2007/0019(COD), 15 (Amendment 17).

The only justification offered for the proposed ban on the use of mmt<sup>®</sup> was the assertion that use of mmt<sup>®</sup> “is very damaging to the environment” and that it could “easily be replaced with less damaging substances.”<sup>34</sup> The Environment Committee’s amendment was approved in November 2007.

Pursuant to the “co-decision” procedure set forth in Article 251 of the EU Treaty, the Parliament, the Council, and the Commission thereafter proceeded to debate the proposed amendments to Directive 98/70. During the course of the debate, the Commission reaffirmed its earlier conclusions specifically as they related to mmt<sup>®</sup>, noting “[t]he Commission is not aware of any information that would lead it to draw different conclusions now to those drawn at the time that the Impact Assessment was prepared.”<sup>35</sup> Ultimately, however, the debate prompted a political compromise among the institutions relating to mmt<sup>®</sup>. The EU institutions agreed to add a new Article 8a to Directive 98/70, which, among other things, states:

1. The Commission shall conduct an assessment of the risks for health and the environment from the use of metallic additives in fuel and, for this purpose, develop a test methodology. It shall report its conclusions to the European Parliament and to the Council by 31 December 2012.
2. Pending the development of the test methodology referred to in paragraph 1, the presence of the metallic additive methylcyclopentadienyl manganese tricarbonyl (MMT) in fuel shall be limited to 6 mg [milligrams] of manganese per litre from 1 January 2011. The limit shall be 2 mg of manganese [Mn] per litre from 1 January 2014.
3. The limit for the MMT content of fuel specified in paragraph 2 shall be revised on the basis of the results of the assessment carried out using the test methodology referred to in paragraph 1. It may be reduced to zero where justified by the risk assessment. It cannot be increased unless justified by the risk assessment. Such a measure, designed to amend non-essential elements of this Directive shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 11(4).

The final text was agreed to by the Parliament and Council and adopted in accordance with Article 95 of the EC Treaty as Directive 2009/30/EC on April 23, 2009. It was published in the *Official Journal* on June 5, 2009.<sup>36</sup>

In July 2009, Afton Chemical Limited (Afton’s English affiliate) initiated a legal action in the United Kingdom (U.K.) with the intent of seeking a reference from the U.K. court to the ECJ to resolve whether the new Article 8a was lawful.<sup>37</sup> On August 26, 2009, the U.K. court referred sev-

eral questions to the ECJ for resolution, one of which was whether Article 8a is “[u]nlawful as being in violation of the precautionary principle.”<sup>38</sup>

## B. The Decision

Neither Article 8a nor the recital from Directive 2009/30/EC concerning that article specifically refers to the precautionary principle. Nonetheless, Afton anticipated that the EU institutions would rely on the precautionary principle as a basis for the adoption of Article 8a, and those institutions did, in fact, do so in their arguments before the ECJ.

Afton argued that the precautionary principle should not apply to support imposition of limits on use of mmt<sup>®</sup> for two principal reasons, one substantive in nature, and the second procedural. First, Afton argued that more than sufficient scientific information was available to assess the risks to health or the environment presented by the additive as reflected in the many assessments of mmt<sup>®</sup> completed by government and independent bodies over the last three decades.<sup>39</sup> As evidence, Afton pointed to the facts, among others, that mmt<sup>®</sup> was approved for use in Canadian gasoline at a level of 18 mg Mn/liter (and had been so for decades), Chinese gasoline at a level of 16 mg Mn/liter, and U.S. conventional gasoline at a level of 8.3 mg Mn/liter. That each of these nations (and others) had reviewed the available scientific information and determined that use of mmt<sup>®</sup> was acceptable obviated any need to take action on a “precautionary” basis.

Second, Afton argued that the requisite scientific assessment necessary to support application of the precautionary principle identified both in the Commission’s guidance on the precautionary principle and prior legal precedent in Europe had not been undertaken by any of the EU institutions. Rather, the institutions had agreed to a “political” compromise on limits without any scientific justification either regarding the need for limits on use, or the specific use limits ultimately adopted. As evidence supporting this argument, Afton pointed to the inability of the EU institutions to provide any such scientific assessment in response to a formal request for such information under the European access to information regulation.

38. O.J. (C 267/44) (2009).

39. See, e.g., Y. Zhang et al., *Emissions of MMT for Light-Duty Vehicles*, 19 RESEARCH ENVTL. SCI., 2006 (China); Fuel Additive MMT: Petition to the Commissioner of Environment and Sustainable Development, No. 32, Health Canada (Nov. 2001) (Canada); 59 Fed. Reg. 42227 (Aug. 17, 1994) (United States); Risk Assessment for the Combustion Products of Methylcyclopentadienyl Manganese Tricarbonyl (MMT) in Gasoline, Health Canada (Dec. 6, 1994) (Canada); Lead in Gasoline: Alternatives to Lead in Gasoline Supplementary Report, Royal Society of Canada (Feb. 1986) (Canada); An Assessment of the Effect of MMT on Light-Duty Vehicle Exhaust Emissions in the Canadian Environment, Canadian General Standards Board, Gasoline and Alternative Automotive Fuels Committee (Apr. 4, 1986) (Canada); Methylcyclopentadienyl Manganese Tricarbonyl (MMT) An Assessment of the Human Health Implications of Its Use as a Gasoline Additive, Ministry of National Health and Welfare (78-EHD-21 1978) (Canada); The Environmental Implications of Manganese as an Alternative Antiknock, SAE Paper No. 750926 (Oct. 15, 1975) (United States); 38 Fed. Reg. 33734, 33738 (Dec. 6, 1973) (United States).

34. *Id.*

35. Non-Paper MMT, 3.

36. O.J. (L 140) 5.6.2009, 88-113 (2009).

37. See *Afton Chemical Limited v. Secretary of State*, Case No. CO/6906/2009.



Although the ECJ apparently agreed with elements of Afton's second argument, the Court ultimately concluded that Article 8a "is not invalid by reason of the infringement of the precautionary principle."<sup>40</sup> This was so even though the ECJ reaffirmed what it had stated in *European Commission* several months earlier:

A correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health . . . and, secondly, *a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research.*<sup>41</sup>

Regarding the second of these two criteria, the ECJ agreed that none of the EU institutions had actually completed such a comprehensive assessment. As the ECJ put it, "it is clear from the scientific documents and from the debate between the parties that, when Directive 2009/30 was adopted, *no public body or independent entity had undertaken a scientific assessment of the effects of MMT,*" either concerning "health" or concerning vehicle operation as reflected in the competing studies "carried out by the motor car industry or by the producers of MMT."<sup>42</sup>

This failure was not fatal to application of the precautionary principle, however, for two apparent reasons. First, the ECJ recognized that "the European Union's broad discretion, which implies limited judicial review of its exercise, applies not only to the nature and scope of the measures to be taken *but also, to some extent, to the finding of the basic facts.*"<sup>43</sup> To that end, the ECJ acknowledged that the Parliament, the Council, and the Commission "took into account" several scientific studies during the course of the legislative process "in order to exercise their discretion properly."<sup>44</sup>

Second, the ECJ put considerable emphasis on the fact that the limits for mmt\* are "temporary" in nature and subject to potential revision based on further scientific review.

Article 8a(1) of Directive 98/70 provides for the development of test methodologies and the presentation of conclusions before the Parliament and the Council by 31 December 2012. . . . The limit for the MMT content of fuel was accordingly set pending the development of such test methodologies. *It is therefore temporary and is capable of amendment according to the results of developments which may be observed.*<sup>45</sup>

In this way, the ECJ concluded that the EU legislature had appropriately balanced its obligation to afford a high level of environmental protection while protecting the economic interest of traders:

[T]he European Union legislature could justifiably take the view that the appropriate manner of reconciling the high level of health and environmental protection and the economic interests of producers of MMT was to limit the content of MMT in fuel on a declining scale while providing for the possibility, in Article 8a(3) of Directive 98/70, of revising those limits on the basis of the results of assessment.<sup>46</sup>

In short, the commitment written into the legislation to conduct a "future" review of the science was deemed sufficient by the ECJ to satisfy the second prerequisite for application of the precautionary principle—namely, "a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research."

### C. Discussion

For those who fear that the precautionary principle can be misused to allow "politics" to supplant science as a basis for environmental decisionmaking, the decision in *Afton Chemical Limited* ought to be concerning. The decision in *Afton Chemical Limited* effectively sanctions an "act now and assess later" approach to environmental regulation. Such an approach is problematic for a number of reasons.

First, the "act now and assess later" approach sanctioned by the ECJ potentially sidesteps legal obligations imposed by international trade agreements, including those developed by the World Trade Organization (WTO). For example, Article 2.2 of the WTO's Agreement on Technical Barriers to Trade (TBT Agreement) prohibits WTO members (one of which is the EU) from adopting technical regulations that have "the effect of creating unnecessary obstacles to international trade." To meet this requirement, technical regulations must not be "more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create." Article 2.2 of the TBT Agreement further provides that "[i]n assessing such risks, relevant elements of consideration" include "available scientific and technical information."<sup>47</sup> Because the "act now and assess later" approach allows for the imposition of technical restrictions *before* completion of a risk assessment, it cannot appropriately guarantee that the technical restriction, *when it first goes into effect*, meets the not "more trade-restrictive than necessary" requirement.<sup>48</sup>

40. *Afton Chemical Limited*, ¶ 69.

41. *Id.* ¶ 60 (emphasis added). Notably, the same day that the ECJ issued its decision in *Afton Chemical Limited*, the Commission reiterated in a response to a question from a member of the European Parliament that the Commission's communication on the precautionary principle "calls for an adequate scientific evaluation *before* there is recourse to the precautionary principle." See <http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=E-2010-3147&language=EN>, ¶ 2 (emphasis added).

42. *Afton Chemical Limited*, ¶ 58.

43. *Id.* ¶ 33 (emphasis added).

44. *Id.* ¶¶ 36-42.

45. *Id.* ¶¶ 52-53 (emphasis added).

46. *Id.* ¶ 64.

47. The WTO's Agreement on Technical Barriers to Trade can be obtained at <http://www.wto.org>.

48. On February 13, 2009, the EU provided notice to other WTO Members of adoption of the new fuel quality directive as required by the WTO's TBT Agreement. See Notification G/TBT/N/EEC/250, *available at* <http://tbtims.wto.org>. The author is not aware that any WTO Member commented on the issue of mmt\*. As mmt\* was only a very minor part of the overall fuel quality directive, however, the potential implications of the mmt\* re-

Second, by deferring assessment of the “available scientific and technical information,” the “act now and assess later” approach sanctioned by the ECJ empowers the EU legislature to act based on a highly selective and potentially biased subset of the available “science.” The ECJ upheld the EU legislature’s regulation of mmt<sup>®</sup> in part because the Parliament and the Council “took into account” a handful of “studies” that included: (a) “the Sierra Research report of 29 August 2008”<sup>49</sup>; (b) a study “carried out in 2004 by the International Council on Clean Transportation”<sup>50</sup>; and (c) the 2006 “Declaration of Brescia.”<sup>51</sup> Whatever the merit or lack thereof of each of these so-called studies, they do not even remotely comprise the full range of scientific data available for mmt.<sup>52</sup> The ECJ apparently recognized as much when it separately observed, “MMT has long been the subject of studies and risk analyses.”<sup>53</sup> The rationalization of a desired outcome is almost always easier when facts that don’t support the outcome can be overlooked or ignored. It is for this reason that risk assessments typically rely on a “weight of evidence” approach based on review of *all of the available scientific data*.<sup>54</sup> Only by reviewing all of the relevant data can one have reasonable confidence that the resulting conclusions have merit. The “act now and assess later” approach lacks this critical component.

Third, the “act now and assess later” approach sanctioned by the ECJ potentially opens the door for application of a standard for review that would be practically impossible for any product to meet. Article 8a(3) of Directive 98/70 provides that the limits for mmt<sup>®</sup> may be changed if “justified” based on “the results of the assessment carried out using the test methodology referred to in [Article 8a(1)].” Precisely what is meant by the term “justified” is unclear because the term is not defined. However, the “recital” that addresses Article 8a (Recital 35) states: “This limit should be revised upwards only if the use of higher dosage rates can be demonstrated *not* to cause adverse effects.” (Emphasis added.) At its most extreme, proving that a product will not cause any adverse effects presumes that the product could be tested or evaluated *under all possible circumstances*. Such testing is simply not possible. For this reason, the Commission presumably will adopt a more reasonable standard, but until the Commission actually

proposes a framework for the assessment, the possibility of an unachievable “prove the negative” standard cannot be discounted. Unfortunately, the ECJ decision provides no guidance on this important issue.

Finally, and more generally, the “act now and assess later” approach might actually result in an increased risk to public health or the environment, particularly in the case of a complex substance such as gasoline. Several years ago, the U.S. Environmental Protection Agency (EPA) compiled a master list of more than 1,000 compounds emitted from motor vehicles.<sup>55</sup> From this list, EPA identified nearly 150 compounds that present potential cancer or non-cancer threats to human health or threats to the environment. Included among these compounds were metals, such as manganese, nickel, and chromium, and a wide range of hydrocarbons, including benzene, 1,3 butadiene, formaldehyde, acetaldehyde, acrolein, polycyclic organic matter (POM), and naphthalene, among others.

Many of the compounds identified by EPA as potential threats are found in gasoline. Benzene, acrolein, and 1,3 butadiene are natural hydrocarbon components or combustion byproducts of gasoline. Other compounds on EPA’s list are combustion byproducts of materials intentionally added to gasoline by refiners and gasoline blenders, including manganese from mmt<sup>®</sup>, acetaldehyde from methyl tertiary butyl ether (MTBE), and formaldehyde from ethanol. (mmt<sup>®</sup>, MTBE, and ethanol are fuel additives used to increase octane.) The concentration of individual compounds found in gasoline typically varies, however, depending upon the range of options available to the gasoline producer. Concentrations vary because changes in one parameter of gasoline, e.g., benzene concentrations, often require parallel alterations in another parameter, e.g., increased use of ethanol, MTBE, mmt<sup>®</sup>, or other fuel components, to ensure that gasoline meets consumer expectations for performance.

For this reason, regulatory authorities in some parts of the world have long recognized that decisions concerning gasoline composition must account for the full range of constituents in gasoline and how changes in one constituent may impact another. Language in the U.S. Clean Air Act (CAA)<sup>56</sup> provides a clear example:

No fuel or fuel additive may be prohibited by the Administrator . . . unless he finds, and publishes such finding, that in his judgment such prohibition *will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited.*<sup>57</sup>

The same should be true for any potential application of the “precautionary principle” to decisionmaking concerning the composition of gasoline. As noted above, the

strictions for application of the precautionary principle more generally in Europe may not have been fully appreciated at the time.

49. *Afton Chemical Limited*, ¶ 36.

50. *Id.* ¶ 37.

51. *Id.*

52. The witness statements of Stanley Charles King and Peter Kynoch Sellar submitted in support of the U.K. action from which questions were referred to the ECJ for resolution, describe literally dozens of government and independent assessments of mmt<sup>®</sup> and individual technical studies concerning mmt<sup>®</sup> completed over the course of more than three decades in Africa, Asia, North America, and elsewhere around the globe. The ECJ decision makes no reference to these scientific studies and analyses.

53. *Afton Chemical Limited*, ¶ 73.

54. See, e.g., *European Food Safety Authority; Application of Systematic Review Methodology to Food and Feed Safety Assessments to Support Decisionmaking*. 8 EFSA J. 52 (2010), available at <http://www.efsa.europa.eu>, (“Reference could be made to the total number of papers screened and of those included and the total number of subjects (reported in the results section) in order to describe the weight of evidence gathered.”).

55. EPA’s master list is available on the internet at <http://www.regulation.gov> in Docket No. EPA-HQ-OAR-2005-0036 (Item 0055).

56. 42 U.S.C. §§7401-7671q, ELR STAT. CAA §§101-618.

57. 42 U.S.C. §7545(c)(3).

threat to human health from gasoline combustion is multidimensional in nature. The removal or reduction of one potentially dangerous component of gasoline can prompt increased use of another potentially dangerous component. As a result, any application of precaution to deal with the threats presented by gasoline combustion must also be multidimensional. This is confirmed by recent guidance issued by the government of Canada relating to the application of “precaution” in scientific decisionmaking. The Canadian guidance highlights the critical importance of “comparative” assessments whenever trade offs must be made.

Precautionary measures should be cost-effective, with the goal of generating (i) an overall net benefit for society at least cost, and (ii) efficiency in the choice of measures. . . . *Consideration of risk-risk tradeoffs or comparative assessments of different risks would generally be appropriate. . . .*<sup>58</sup>

In short, a multidimensional threat like that presented by gasoline combustion requires a multidimensional risk assessment framework, even when pursuing action in a precautionary way. The “act now and assess later” approach sanctioned by the ECJ empowers the EU legislature to focus exclusively on a single component of gasoline (in this case mmt<sup>®</sup>) *without proper consideration of the multidimensional nature of the threat posed by gasoline combustion*. As a result, such an approach may have the unintended result of increasing overall risks to public health or welfare.

### III. Conclusion

In today’s world, science provides a credible means on which to base environmental policy because science (done

right) is all about facts, and facts when properly marshaled provide perhaps the most effective means for choosing among an array of often contentious policy outcomes. As Commission guidance and past judicial decisions concerning the precautionary principle make clear, science and the precautionary principle are (or at least should be) inextricably linked.

The overarching problem with the decision in *Afton Chemical Limited* is that it sanctions application of the precautionary principle to restrict use of products in Europe without even the most rudimentary scientific assessment, provided the restriction is “temporary” in nature, and the restriction is coupled with a directive for some sort of “future” scientific review. So long as the EU institutions can refer to one or more random studies and the existence of some amount of “uncertainty,” they can now justify reliance on the precautionary principle without any scientific assessment at all. This “act now and assess later” approach effectively renders the Commission’s prior guidance on the precautionary principle obsolete and greatly enhances the risk of arbitrary decisionmaking. It potentially opens the floodgates for any number of “temporary” regulatory restrictions without adequate scientific justification and based purely on a “political” application of the precautionary principle. For anyone doing business in Europe, how the Commission proceeds with its assessment of metallic additives ought to be of considerable interest as the Commission’s actions may set the bar for future regulatory action in Europe involving the precautionary principle.

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58. GOVERNMENT OF CANADA, A FRAMEWORK FOR THE APPLICATION OF PRECAUTION IN SCIENCE-BASED DECISION MAKING ABOUT RISK 12 (2003) (emphasis added).