



December 7, 2004

Division of Dockets Management  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

Re: Proposed Rule Regarding Albuterol Metered Dose Inhalers (Docket No. 2003P-0029)

Gentlemen/Ladies:

This letter is response from Honeywell International Inc. ("Honeywell") to a letter of October 20, 2004, from the Natural Resources Defense Council to the Docket in the above-referenced rulemaking. NRDC's letter responds to August 16, 2004, comments filed by Honeywell during the comment period.

In its letter, NRDC asserts (1) that the prohibition on new production capacity in Montreal Protocol Decision VII/9, ¶ 7, applies to production for "essential uses" as well as to production to meet the "basic domestic needs" of Article 5 countries; (2) that the asserted prohibition is binding on U.S. production, even though it is inconsistent with the Clean Air Act and applicable EPA regulations; and, (3) that Honeywell will be commissioning new capacity in order to produce CFCs in the United States for MDI. These assertions incorrectly state the applicable law and facts in this matter.

1. Decision VII/9 Is Not Binding in the United States

Under the Clean Air Act ("CAA") and implementing regulations, Honeywell may produce CFC-11/12 in the United States so long as it holds production allowances that have been allocated and subsequently properly conferred on Honeywell. NRDC's letter takes the position that lawfully allocated and conferred allowances are nullified by Decision VII/9, adopted by the Parties to the Montreal Protocol. But Decision VII/9 is not binding in the United States with respect to either production for MDI or for the basic domestic needs of Article 5 countries.

In order to become binding in the United States, Decision VII/9 would have to either (1) be ratified by the United States Senate as an amendment to the Montreal Protocol; or, (2) be enacted into the CAA by the United States Congress. Since Decision VII/9 has neither been ratified by the United States Senate nor enacted as an amendment to the CAA, NRDC's letter attempts to find authority in the existing CAA that would



03P-0029

C35

make it effective in this country. The letter cites Section 614 of the CAA, 42 U.S.C. 7671m(b), which requires that the stratospheric ozone protection program of the Clean Air Act be construed consistently with the "Montreal Protocol." "Where the Montreal Protocol imposes a prohibition on the Parties," NRDC says, "the CAA makes that prohibition part of U.S. law." (NRDC Letter, at 7.)

This argument ignores, however, Section 601(9) of the CAA, 42 U.S.C. 7671(9). Section 601(9), adopted into law in 1990, defines the "Montreal Protocol" in entirely retrospective terms to include, in addition to the text of the Protocol itself, "adjustments adopted by the Parties thereto and amendments *that have entered into force.*" [emphasis supplied] Decisions or other "adjustments" or "amendments" to the Protocol reached subsequent to the enactment of the 1990 CAA Amendments are not included in the statutory definition. Thus NRDC is incorrect in asserting that Section 614 of the CAA makes a subsequent Decision "a part of U.S. law."

Even if the CAA were not clear on this point, the suggestion that prohibitions subsequently adopted under the Montreal Protocol become "a part of U.S. law" without further action would have to be rejected. Under the U.S. Constitution, the provisions of treaties are not self-executing. They do not enter into force until signed by the President and ratified by the Senate.<sup>1</sup> The Congress cannot prospectively ratify international agreements. Furthermore, NRDC's contention must be rejected because it is inconsistent with the fundamental rule that no legislature may bind a subsequent one.

For these reasons, Decision VII/9 does not prevent a company that possesses validly issued and conferred allowances from using them as authority to produce CFCs in the United States for use in MDIs or for sale to meet "basic domestic needs" in Article 5 countries.

## 2 Decision VII/9 Does Not Affect Production for Use in Metered Dose Inhalers

Even if Decision VII/9 were binding in the United States, it would not prevent Honeywell from producing CFCs for MDI. In its comments, Honeywell observed that "Decision VII/9 by its terms does not apply to 'essential use' production." NRDC's argument to the contrary is not persuasive.

The preamble to Decision VII/9 states its purposes: to assure adequate supplies of CFCs for the basic domestic needs of Article 5 (developing) countries, and to prevent monopolization of the supply of CFCs for the basic domestic needs of Article 5 countries.<sup>2</sup> Paragraphs 1-8 of Decision VII/9 adopt four policies to accomplish these purposes: (1) encouraging Article 5 countries to supply CFCs for the basic domestic needs of other Article 5 countries; (2) urging the Parties to the Montreal Protocol to monitor to prevent oversupply; (3) prohibiting installation of new CFC capacity; and, (4)

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<sup>1</sup> U.S. Const., Art. II, §2.

<sup>2</sup> NRDC agrees that these are the purposes of Decision VII/9. See NRDC letter at 5.

urging the Parties to agree to a licensing system and production baselines for Article 5 countries. It is obvious from the structure, content, and language of ¶¶ 1-8 that the four policies are all designed to regulate CFC production for the “basic domestic needs” of Article 5 countries in order to accomplish the two objectives of the Decision.

NRDC seeks to expand the reach of Decision VII/9 to cover essential uses by reading ¶ 7 of the Decision in isolation from the title, the four paragraphs of preambular material, and the other seven paragraphs of policy statements contained in the Decision, all of which refer only to the “basic domestic needs” of Article 5 countries. The text of the Decision is entirely consistent with its title “Basic Domestic Needs.” The text mentions Article 5 in eight different paragraphs. The term “essential use” appears nowhere in Decision VII/9. The limited applicability of ¶ 7 is therefore clear on the face of the Decision.

NRDC’s other points are equally unavailing. Admitting that it can find no “context” to suggest that Decision VII/9 was intended to apply to “essential uses,” NRDC says that nothing in the Montreal Protocol *limits* the prohibition of ¶ 7 to “basic domestic needs.” NRDC’s statement misses the point: what matters is that nothing in Decision VII/9 *imposes* any prohibition on production of CFCs for “essential uses.”

NRDC further argues that it would not be inconsistent with the object and purpose of Decision VII/9 to apply the prohibition of ¶ 7 beyond the “basic domestic needs” of Article 5 countries, and that indeed, some countries have made such a choice. But again these comments miss the point, which is that nothing in Decision VII/9 *requires* countries to prohibit lawfully authorized production for uses other than the “basic domestic needs” of Article 5 countries. Likewise, the fact that some countries have *voluntarily chosen* to go beyond the terms of Decision VII/9 provides no support for the contention that a broader prohibition is *required* by the Decision.

### 3. The New Production Capacity Issue

In its comments on the proposed rule, Honeyweil stated that it intends to transfer production of CFCs for use in MDIs from its factory in Weert, the Netherlands back to Baton Rouge, Louisiana, where CFCs-11, 12, and 114, were produced before Decision VII/9 was adopted. NRDC insists that this transfer is prohibited by ¶ 7 of the Decision. This is incorrect, for the following reasons.

First, as explained above, the prohibition on new production capacity of Decision VII/9 applies to production for the “basic domestic needs” of Article 5 countries, not to production for “essential uses.” Moreover, nothing in the Clean Air Act or applicable EPA regulations restricts production for “essential uses” based on whether or not new capacity was commissioned to produce it. The terms used by NRDC – “new capacity,” “commission,” “decommission,” “mothball,” do not appear in the applicable EPA regulations.

Even if the terms of Decision VII/9 were thought applicable to production for “essential uses,” however, it would not prevent Honeywell from recommencing production of CFC 11/12 at its Baton Rouge plant, because Honeywell is not commissioning new production capacity. Honeywell produced CFC-11/12 and other fluorochemical products in multiple units at the Baton Rouge facility at least as far back as 1974. Furthermore, Honeywell continued to produce CFC-11/12 at the Baton Rouge facility after December 7, 1995, continuing until the end of that year. As Honeywell said in its comments, no new production capacity is needed or contemplated to produce CFC-11/12 at the Baton Rouge facility now. Even if some modification of the existing production units were necessary, existing production capacity would not thereby become “new.” Sources regulated under Title VI are not subject to the applicability rules for “new source review” or any other such process under the Clean Air Act.

To sum up, NRDC’s letter fails to establish that the prohibition on new production contained in Decision VII/9 applies to Honeywell’s plan to transfer its authorized CFC production from The Netherlands to the United States. In the first instance, unless ratified or enacted into U.S. law, Decision VII/9 does not apply in the U.S. Even if it did, the Decision by its own terms applies only to production of CFC’s for the “basic domestic needs of Article 5 countries, not to production for MDI essential uses. Finally, even if the Decision were read to prohibit new production capacity for “essential uses,” it would not apply to Honeywell’s Baton Rouge facility, because no new production capacity is needed or contemplated there.

Honeywell appreciates the opportunity to provide the FDA with this response to the NRDC letter, and asks that this letter be included in the docket for this matter and considered by the FDA as it reaches its decision.

Sincerely yours,



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