



NATURAL RESOURCES DEFENSE COUNCIL

October 20, 2004

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

RE: Docket No. 03P-0029: Proposed Rule on the Non-Essentiality of Albuterol Metered Dose Inhalers (MDIs); Installation and Commissioning of New CFC Production Capacity by Honeywell

Dear Sir or Madam:

This letter is in response to the comments submitted to the above-referenced docket by Richard E. Ayres on behalf of Honeywell International, Inc. on August 16, 2004.¹ The Honeywell letter was in response to a May 13, 2004, letter from the Natural Resources Defense Council ("NRDC") to the Environmental Protection Agency, in which we stated that Honeywell's proposed production of CFC-11 and CFC-12 at its Baton Rouge, Louisiana, facility would violate Decision VII/9 of the Montreal Protocol and the Clean Air Act ("CAA").² NRDC requests FDA to consider this response to the Honeywell letter as the agency evaluates comments to the proposed rule on albuterol non-essentiality.

The Honeywell letter contains several incorrect statements of law and fact. The letter asserts that: (a) Montreal Protocol Decision VII/9's prohibition on new production capacity is limited to production for "basic domestic needs"; (b) nothing in Title VI of the CAA restricts production capacity as provided by Decision VII/9; and (c) Honeywell's proposed starting of production of CFC-11/12 at its Baton Rouge facility would not constitute the installation or commissioning of new production capacity as prohibited by Decision VII/9. As demonstrated below, these assertions are not correct.

FDA Docket 03P-0029, Doc. # EMC-37 ("Honeywell letter").

² FDA Docket 03P-0029, Doc. # C-12 ("May 14, 2004 NRDC Letter").

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A. Montreal Protocol Decision VII/9's Prohibition on New Production Capacity is Not Limited to Production for "Basic Domestic Needs"

The Honeywell letter asserts that because Montreal Protocol Decision VII/9 is titled "Basic domestic needs", it applies only to ozone-depleting substances ("ODS") exported to developing countries for basic domestic needs, and therefore does not apply to the proposed new production of CFC-11/12 for essential uses at Honeywell's Baton Rouge plant.³ Based on accepted principles of treaty interpretation, this is a flawed reading of Decision VII/9.

The accepted principles of treaty interpretation are codified in the Vienna Convention on the Law of Treaties ("Vienna Convention").⁴ The Vienna Convention provides, in relevant part, that:

A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. * * * There shall be taken into account, together with the context . . . any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions . . . [and] any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation⁵

³ Honeywell letter at 3-4. In Protocol terminology, "basic domestic needs" is a complex term that refers to: (1) an exception to the general phase-out of ODS production by developed countries ("non-Article 5 Parties") for uses related to the needs of developing countries ("Article 5 Parties"), see Montreal Protocol at Arts. 2A-2F, 2H; and (2) a limit on ODS production and consumption by Article 5 Parties during the "grace period" in which such Parties are allowed to delay implementation of the Article 2 phase-out, see Montreal Protocol at Art. 5. The Honeywell letter appears to have confused these two distinct elements of "basic domestic needs". See Honeywell letter at 2.

⁴ Vienna Convention on the Law of Treaties, 1155 U.N.T.S. 331, *entered into force* January 27, 1980.

⁵ Id. at Arts. 31(1) and 31(3)(b). As used in the Vienna Convention, "'treaty' means an international agreement concluded between States in written form and governed by international law, . . . whatever its particular designation." Id. at Art. 2(1)(a). Thus, the term "treaty" includes Decisions of the Parties to the Montreal Protocol. Although the United States is not a Party to the Vienna Convention, it has recognized the Convention as an authoritative statement of the law on treaties. Restatement (Third) of Foreign Relations Law of the U.S. pt. 3, Introductory Note (stating that the United States "accepts the Vienna Convention as presumptively codifying the customary international law governing international agreements, and therefore as foreign relations law of the United States even though the United States has not adhered to the Convention.") The Department of State has stated that "[a]lthough not yet in force, the Convention is already generally recognized as the authoritative guide to current treaty law and practice." S. Exec. Doc. L., 92nd Cong., 1st Sess. (1971) p.1. Indeed, the Environmental Protection Agency recently has recognized the Vienna Convention as customary international law

1. “Ordinary Meaning”

As indicated above, the first step in interpreting treaty text is to look at the “ordinary meaning” of the terms. Decision VII/9, paragraph 7 reads:

[F]rom 7 December 1995, no Party should install or commission any new capacity for the production of controlled substances listed in Annex A or Annex B of the Montreal Protocol.⁶

On its face, this provision clearly applies to all production capacity for CFCs in Annex A (including CFC-11 and CFC-12). There is no exception for “essential uses,” nor is this provision limited to production capacity for “basic domestic needs” of Article 5 Parties. Thus, the terms of the provision do not support a reading limiting the measure to production for basic domestic needs.

The Vienna Convention specifies that in addition to the substantive words of a treaty, “text” includes a treaty’s preamble and annexes.⁷ However, nothing is said about titles or headings. Moreover, U.S. courts have held that general rules of statutory construction apply to interpreting treaties.⁸ Those rules provide that a title may not be used to create ambiguity when the terms of a provision are clear,⁹ and cannot control the plain words of a provision.¹⁰ Only in a case of ambiguity in the terms may the title be used to resolve uncertainty or correct obvious errors.¹¹ Moreover, even then, a title is not the first source of guidance outside of the text.

in relation to interpretation of Decisions of the Montreal Protocol. See Protection of Stratospheric Ozone: Request for Information on Existing and Available Stocks of Methyl Bromide, 69 Fed. Reg. 52403, 52404 (Aug. 25, 2004). Also, the International Court of Justice has held that Article 31 of the Vienna Convention reflects customary international law. Libya v. Chad, 1994 ICJ 4, par. 41. U.S. courts apply these same rules to treaty interpretation. See, e.g., Eastern Airlines, Inc. v. Floyd, 499 U.S. 530, 534, 111 S.Ct. 1489, 1493 (1991); United States v. Alvarez-Machain, 504 U.S. 655, 663, 112 S.Ct. 2188, 2193 (1992); Marquez-Ramos v. Reno, 69 F.3d 477, 480 (10th Cir. 1995).

⁶ Decision VII/9, par. 7, United Nations Environment Programme, Report of the Seventh Meeting of the Parties to the Montreal Protocol, UNEP/OzL.Pro.7/12 (Dec. 27, 1995).

⁷ Vienna Convention at Art. 31(2).

⁸ See, e.g., Kahn Lucas Lancaster, Inc. v. Lark International, Ltd., 186 F.3d 210, 215 (2nd Cir. 1999) (stating that “[t]reaties are construed in much the same manner as statutes”); Eastern Airlines, supra, 499 U.S. at 535 (stating that, after the text and its context, “[o]ther general rules of construction may be brought to bear on difficult or ambiguous passages”).

⁹ See, e.g., United States v. Minker, 350 U.S. 179, 76 S.Ct. 281 (1956).

¹⁰ See, e.g., Brotherhood of Railroad Trainmen v. Baltimore & O.R. Co., 331 U.S. 519, 67 S.Ct. 1387 (1947); Pike v. United States, 340 F.2d 487 (9th Cir. 1965).

¹¹ See I.N.S. v. National Center for Immigrants’ Rights, Inc., 502 U.S. 183, 112 S.Ct. 551 (1991); Goodcell v. Graham, 35 F.2d 586 (9th Cir. 1929), *cert. denied* 281 U.S. 708, 50 S.Ct. 240 (1929).

Rather, to resolve ambiguity, U.S. courts refer first to the history of the treaty, negotiations of the parties, and the practical construction adopted by the parties.¹² But in this case there is no ambiguity – the terms of Decision VII/9 clearly are not limited in application to ODS for basic domestic needs. Thus, Decision VII/9's title is irrelevant for interpreting the scope of paragraph 7.

The balance of the text of Decision VII/9 likewise supports the conclusion that the Decision is not limited in scope to ODS for basic domestic needs. Indeed, six of the eight paragraphs of this Decision (including paragraph 7) apply to all ODS and on their face are not limited only to ODS for basic domestic needs. For example, paragraphs 3 and 8 of Decision VII/9 apply to the use of import and export licenses by all Parties for all ODS. Paragraph 3 states:

[I]n order to prevent oversupply and dumping of ozone-depleting substances, all Parties importing and exporting ozone-depleting substances should monitor and regulate this trade by means of import and export licenses.¹³

Note that under the terms of the Protocol, only Article 5 Parties (*i.e.*, developing country Parties) can import ODS for basic domestic needs.¹⁴ Yet, by its plain terms, this provision of Decision VII/9 applies to all Parties importing ODS – *i.e.*, including non-Article 5 Parties (*i.e.*, developed country Parties). Since non-Article 5 Parties cannot import ODS for basic domestic needs, this provision obviously is not limited to ODS exported or imported for basic domestic needs.

Similarly, paragraph 4 of the Decision relates to reporting by all “exporting Parties” of all ODS exports, not just exports to Article 5 Parties – which would be the case if this provision were limited to basic domestic needs. Thus, clearly, the “ordinary meaning” of the terms of Decision VII/9 is that these provisions apply to ODS for all uses, not just basic domestic needs.

Finally, had the Parties intended these provisions to be limited to ODS for basic domestic needs, they could have explicitly stated so – as they did in paragraphs 1 and 2 of Decision VII/9. Under a long-standing maxim of statutory construction, when the drafters of a provision expressly state something in one place and omit it in another, it is presumed that they did so intentionally.¹⁵ Thus, the presence of the

¹² See O'Connor v. United States, 479 U.S. 27, 33, 107 S.Ct. 347, 351 (1986); Marquez-Ramos, *supra*, 69 F.3d at 480.

¹³ Emphasis added.

¹⁴ Montreal Protocol at Art. 5(1).

¹⁵ See United States v. Wiltberger, 5 Wheat (18 U.S.) 76 (1820); Andrus v. Glover Const. Co., 445 U.S. 608, 661-17, 100 S.Ct. 1905, 1910 (1980); Russello v. United States, 464 U.S. 16, 23, 104 S.Ct. 296, 300 (1983); Duncan v. Walker, 533 U.S. 167, 173, 121 S.Ct. 2120, 2125 (2001).

limiting language in paragraphs 1 and 2 of Decision VII/9, and its absence in the other six, strongly weighs against limiting those six paragraphs – including paragraph 7 – to ODS for basic domestic needs.

2. “Context”

As discussed above, the ordinary meaning of the terms must be viewed in “their context”.¹⁶ The Vienna Convention describes the “context” within which treaty text is to be interpreted as limited to agreements between the parties, or any instrument made by one or more of the parties and accepted by the other parties, in connection with the conclusion of the treaty.¹⁷ Note that this description makes no reference to titles or headings.

Strictly speaking, no such “context” exists for Decision VII/9. However, even if one were to construe this term broadly to include the Framework Convention for the Protection of the Ozone Layer, the Montreal Protocol, and other Protocol decisions, nothing in those agreements provides even the slightest indication that paragraph 7 of Decision VII/9 is to be limited to ODS exports for basic domestic needs. Indeed, as noted below, other Protocol decisions indicate the converse: that paragraph 7 is not so limited.

3. “Object and Purpose”

As noted above, the Vienna Convention provides that a treaty is to be interpreted “in the light of its object and purpose.” Records of the negotiations of the Parties indicate that Decision VII/9 was adopted in lieu of two conflicting proposed Protocol amendments relating to basic domestic needs.¹⁸ The developing countries were concerned about balancing adequate supply during the grace period before the Article 2 phase-out of CFCs applied to them with the need to avoid a monopoly of supply.¹⁹ To meet these joint goals, the Parties adopted several measures in Decision VII/9 that apply generally to ODS production, export, and import. There is no inconsistency with the object and purpose of Decision VII/9 – to protect the various rights and restrictions encompassed by the concept of “basic domestic needs” – and the fact that the majority of the provisions in that Decision have applicability beyond ODS produced for basic domestic needs.

¹⁶ Vienna Convention at Art. 31(1).

¹⁷ Id. at Art. 31(2).

¹⁸ See United Nations Environment Programme, Report of the Twelfth Meeting of the Open-Ended Working Group of the Parties to the Montreal Protocol at 12-15, UNEP/OzL.Pro/WG.1/12/4 (Sept. 18, 1995); Edward A. Parson, *Protecting the Ozone Layer: Science and Strategy*, pp. 229-231 (summarizing the negotiations surrounding Decision VII/9).

¹⁹ See Decision VII/9, 2nd and 3rd preambular pars.

4. Subsequent Practice of the Parties

As noted above, the Vienna Convention provides that the subsequent practice of the parties in applying a treaty should be taken into account when interpreting the treaty's provisions. The subsequent practice of the Montreal Protocol Parties controverts the Honeywell's claim that Decision VII/9 applies only to ODS for basic domestic needs. Specifically, where the Montreal Protocol Parties have implemented the aforementioned provisions of Decision VII/9, they have applied the measures to all ODS, not just those produced for basic domestic needs.

For example, the Ninth Meeting of the Parties adopted Decision IX/8 expressly to implement Decision VII/9's licensing provisions, noting that "decision VII/9 required that an import- and export-licensing system be incorporated into the Montreal Protocol by the Ninth Meeting of the Parties".²⁰ Decision IX/8 covers trade in all ODS, not just imports and exports for basic domestic needs.²¹ Thus, the Parties, acting collectively via Decision IX/8, interpreted the licensing provisions of Decision VII/9 to apply to all ODS production, not just to production for basic domestic needs.

Furthermore, in implementing Decision IX/8 – which was a direct outgrowth of Decision VII/9 – individual Parties uniformly applied its provisions to trade in all ODS. For example, the United States subsequently stated that its licensing requirements – which apply to all exports of ODS, not just those going to Article 5 Parties for basic domestic needs – fulfill the requirements of Decision IX/8.²² Other Parties similarly apply their licensing provisions to all ODS trade, not just that for basic domestic needs.²³

5. Result of Proper Interpretation

As demonstrated above, it is clear from both the ordinary meaning of the terms of Decision VII/9 in their context, and the subsequent practice of the Parties in relation to Decision VII/9, that paragraph 7 of that Decision is not limited to ODS production capacity for basic domestic needs. Therefore, the title of the Decision has

²⁰ Decision IX/8, 3rd preambular par. , United Nations Environment Programme, Report of the Ninth Meeting of the Parties to the Montreal Protocol, UNEP/OzL.Pro.9/12 (Sept. 25, 1997).

²¹ Id. at pars. 1-4.

²² See Protection of Stratospheric Ozone: Reconsideration of Petition Criteria and Incorporation of Montreal Protocol Decisions, 63 Fed. Reg. 41626, 41629-30 (Aug. 4, 1998) (Dir. Final Rule).

²³ See, e.g., European Community, Parliament and Council Regulation 2037/2000 on Substances that Deplete the Ozone Layer, Arts. 6 and 12, 2000 O.J. (L 244) 1, 4; Canada, Ozone-Depleting Substances Regulation, 1998, par. 32, 133 C. Gaz.(II) 101, 114 (Dec. 16, 1998); Japan, The Law Concerning the Protection of the Ozone Layer Through the Control of Specified Substance and Other Measures, Law No. 53 of May 20, 1988 (as amended), Arts. 5 and 6.

no bearing on the scope of that paragraph. The interpretation asserted by the Honeywell letter is inconsistent with established principles of international and U.S. law applicable to the interpretation of international agreements such as Decision VII/9.

B. The Clean Air Act Requires Compliance with Decision VII/9's Prohibition on New Production Capacity

Honeywell's letter claims that "nothing in Title VI of the Clean Air Act . . . restricts production by those who hold 'essential use' allowances based on whether or not 'new capacity' would be required."²⁴ This is an incorrect statement of the law.

Section 614 of Title VI (i.e., subchapter VI) of the CAA establishes the relationship between the Montreal Protocol and the CAA. It states:

This subchapter . . . shall be construed, interpreted, and applied as a supplement to the terms and conditions of the Montreal Protocol . . . and shall not be construed, interpreted, or applied to abrogate the responsibilities or obligations of the United States to implement fully the provisions of the Montreal Protocol. In the case of a conflict between any provision of this subchapter and any provision of the Montreal Protocol, the more stringent provision shall govern."²⁵

Section 614 could not be clearer: where the Montreal Protocol imposes a prohibition on the Parties, the CAA makes that prohibition part of U.S. law. This is true not just for obligations under the original Protocol, but also obligations subsequently adopted by the Parties via Decisions such as Decision VII/9. EPA has acknowledged this very point on numerous occasions, stating that "EPA is obligated by section 614 of the CAA to fully implement decisions of the Montreal Protocol, except where the CAA contains more stringent, conflicting provisions."²⁶ Therefore, the assertion that Decision VII/9 is not part of U.S. law is without basis.

Moreover, the Honeywell letter's suggestion that because Honeywell holds "essential-use" allowances it is somehow exempt from Decision VII/9's restriction

²⁴ Honeywell letter at 4.

²⁵ 42 U.S.C. § 7671m(b) (emphasis added).

²⁶ Protection of Stratospheric Ozone: Allocation of Essential-use Allowances for Calendar Year 2002; and Extension of the De Minimis Exemption for Essential Laboratory and Analytical Uses through Calendar Year 2005, 67 Fed. Reg. 6352, 6354 (Feb. 11, 2002); see also Protection of Stratospheric Ozone: Ban on Trade of Methyl Bromide with Non-Parties to the Montreal Protocol, 68 Fed. Reg. 43930, 43932 (July 25, 2003); Protection of Stratospheric Ozone: Reconsideration of Petition Criteria and Incorporation of Montreal Protocol Decisions, 63 Fed. Reg. 41625, 41629 (Aug. 4, 1998).

on production capacity likewise disregards the CAA's express terms.²⁷ Section 604(d)(2) of the CAA clearly states that such essential-use allowances for medical devices are authorized only "to the extent such action is consistent with the Montreal Protocol."²⁸ As noted above, Decision VII/9 is part of the Montreal Protocol for CAA purposes. Therefore, production of CFCs for essential uses is not exempt from the requirements of that Decision.

C. Installation or Commissioning of New Production Capacity will be Necessary for Honeywell to Produce Pharmaceutical-Grade CFC-11/12 in Baton Rouge

The Honeywell letter asserts that "the express terms of Decision VII/9 do not apply" because no new production capacity or commissioning is necessary for Honeywell to produce CFC-11/12 in Baton Rouge.²⁹ The letter's support for this assertion is that: (a) "no equipment outages or mothballing occurred"; (b) "Honeywell continues to produce pharmaceutical grade CFC-114 at the Baton Rouge Facility"; and (c) "CFC production at Baton Rouge has not been 'mothballed' or otherwise out of service".³⁰ However, the letter misreads Decision VII/9, and therefore its rationale does not support the conclusion that Honeywell's actions are in compliance with that Decision.

1. Restarting CFC-11/12 Production Constitutes the Commissioning of New Production Capacity

Decision VII/9 prohibits the installation or commissioning of new production capacity after December 7, 1995. As NRDC noted in its May 13, 2004 letter,³¹ the standard usage of the term "commission" is to "bring into operation," "commence active service" or "put into active service."³² Honeywell has stated that it ceased production of CFC-11/12 in Baton Rouge in 1995.³³ Unless Honeywell ceased its production of CFC-11/12 within the 24-day period after December 7, 1995 (rather than during the 340 days preceding December 7, 1995), starting production of CFC-11/12 at the Baton Rouge facility now clearly would constitute the commissioning --

²⁷ Honeywell letter at 4.

²⁸ 42 U.S.C. § 7671c(d)(2).

²⁹ Honeywell letter at 4.

³⁰ Id.

³¹ May 13, 2004 NRDC Letter at 6.

³² THE NEW SHORTER OXFORD ENGLISH DICTIONARY 452 (1993); WEBSTER'S II NEW COLLEGE DICTIONARY 226 (1995).

³³ Docket 03P-0029, Doc. # C-9, at 1.

i.e., the bringing into operation – of new production capacity for CFC-11/12 not in use on or after December 7, 1995.

Moreover, even if the cessation of CFC-11/12 production in Baton Rouge did occur after December 7, 1995, the restarting of production now still would constitute prohibited commissioning of new production capacity for CFC-11/12. This is not a case in which Honeywell has produced CFC-11/12 intermittently in Baton Rouge since 1995 (*i.e.*, “swing” production). Rather, by its own admission, Honeywell completely stopped producing CFC-11/12 in Baton Rouge in 1995.³⁴ Honeywell has not provided any evidence that it ever claimed during that nine-year period (e.g., in shareholder reports, SEC filings, tax records, etc.) that it had CFC-11/12 production capacity at its Baton Rouge plant. Use of its production capacity now for CFC-11/12 would be counter to Decision VII/9.

2. Switching Production Capacity Currently Being Used to Produce Other Substances to Production of CFC-11/12 Constitutes the Commissioning of New Production Capacity

The Honeywell letter appears to have misinterpreted Decision VII/9 to not apply as long as the production capacity has not been shut down – even if that capacity is not now, or has never been, used to produce CFC-11/12. Note that although the letter states that “no equipment outages or mothballing occurred”, it does not say what is being produced with that equipment. Since Honeywell ceased production of CFC-11/12 nine years ago, the equipment is obviously being used to produce other substances. To use that equipment now to produce CFC-11/12 would require Honeywell to commission it as new production capacity for that specific use, which is expressly prohibited by Decision VII/9.

Similarly, the Honeywell letter’s assertion that Honeywell currently produces pharmaceutical grade CFC-114 in Baton Rouge is irrelevant in this regard. CFC-114 is a different substance than CFC-11 or CFC-12, and thus switching CFC-114 production capacity into CFC-11/12 production capacity constitutes the commissioning of new production capacity for CFC-11/12.

Moreover, based on the public record, it is extremely unlikely that Honeywell will be able to use only its current CFC-114 production capacity to produce the quantity of CFC-11 and CFC-12 that the U.S. requested in its 2006 essential use nomination. The 2006 U.S. essential-use nomination is for 1900 metric tonnes of CFCs.³⁵ Of that, 70 percent, or 1330 metric tonnes, is requested for CFC albuterol

³⁴ Id. at 1.

³⁵ United Nations Environment Programme, Progress Report of the Technology and Economic Assessment Panel at 22 (May 2004).

MDIs.³⁶ Since CFC albuterol MDIs only use CFC-11 and CFC-12, at least 1330 metric tonnes of the U.S. nomination must be for these two CFCs.³⁷

However, the total essential-use allowance allocation in the United States for CFC-114 in 2000 was just 96.4 metric tonnes.³⁸ And in 2001 the only other Party allocated more than 7 metric tonnes of CFC-114 was the European Union.³⁹ Presumably, the European Union obtains its CFC-114 from European suppliers. Therefore, it is reasonable to conclude that less than 100 metric tonnes of Honeywell's Baton Rouge facility's production capacity is being used for CFC-114 production. Thus, to produce 1330 metric tonnes of CFC-11/12, Honeywell would have to use over 1200 metric tonnes of production capacity that currently is not being used to produce CFC-114.

Moreover, Honeywell has stated that it "would need to use less than 10% of its installed capacity at Baton Rouge in order to produce enough product to satisfy the 2006 essential use nominations for CFCs for the United States."⁴⁰ As noted above, the U.S. essential use nomination for 2006 is 1900 metric tonnes. Thus, Honeywell is claiming that its Baton Rouge facility's production capacity is at least 19,000 metric tonnes. Obviously, Honeywell intends to convert equipment, processes, and/or facilities currently being used to produce non-CFC substances in order to reach the CFC-11/12 production capacity to which it has committed.

3. Modifying or Upgrading Equipment, Processes, or Facilities Constitutes the Installation of New Production Capacity

Although Honeywell has stated that it produced CFC-11/12 at its Baton Rouge plant prior to 1996, it has never stated that whether this was pharmaceutical-grade CFC-11/12.⁴¹ NRDC understands from industry experts that to render non-pharmaceutical production capacity for CFC-11/12 capable of producing

³⁶ Id.

³⁷ Note that of the U.S. essential use nomination for 2001 – the last year in which individual CFC quantities were considered – over 92 percent of the amount requested was for CFC-11 and CFC-12. See United Nations Environment Programme, Progress Report of the Technology and Economic Assessment Panel at 110 (April 1999).

³⁸ See Protection of Stratospheric Ozone: Allocation of Essential Use Allowances for Calendar Year 2000: Allocations for Metered-Dose Inhalers and the Space Shuttle and Titan Rockets, 65 Fed. Reg. 716, 721 (Jan. 6, 2000) (this is the last year in which allocations for individual substances were listed).

³⁹ See United Nations Environment Programme, Report of the 11th Meeting of the Parties, at Annex VII, UNEPOzL.Pro.11/10 (Dec. 17, 1999).

⁴⁰ Docket 03P-0029, Doc. # EMC-38, at 1.

⁴¹ Note that the Honeywell letter states that Honeywell's current production of CFC-114 is "pharmaceutical grade", but refers only to past "production" of CFC-11/12. Letter at 1, 3-4.

pharmaceutical-grade CFC-11/12 would require modifications and/or additions to equipment, processes, or facilities. Such modification and/or addition of new equipment, processes, and facilities constitutes the installation of new production capacity, contrary to Decision VII/9.

In addition, as discussed above, it is very likely that Honeywell intends to use production capacity that is currently being used to produce substances that are not CFCs. It is NRDC's understanding from industry experts that additions and/or modifications to non-CFC production equipment, processes, or facilities would almost certainly be required in order to convert that equipment, processes, and facilities into production capacity for CFC-11/12. Doing so would clearly constitute installation or commissioning of new production capacity – in direct contravention of Decision VII/9.

D. Conclusion

Decision VII/9 clearly prohibits the installation or commissioning of new CFC-11/12 production capacity by Honeywell at its Baton Rouge facility – regardless of the purpose for which the CFCs are intended. This prohibition is effective under U.S. law pursuant to Sections 614 and 604 of the Clean Air Act. Based on a plain reading of Decision VII/9, the subsequent practice of the Parties, the facts admitted by Honeywell, and information provided by industry experts, any action by Honeywell to start producing pharmaceutical-grade CFC-11/12 at its Baton Rouge facility would violate Montreal Protocol Decision VII/9 and the Clean Air Act.

FDA's consideration of NRDC's comments in this regard is appreciated.

Sincerely,



David Doniger
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