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613 F.2d 947
198 U.S.App.D.C. 214
MONSANTO COMPANY, Petitioner,
v.
Donald KENNEDY, as Commissioner of Food and Drugs, and
Joseph A. Califano, Jr., as Secretary of Health,
Education and Welfare, Respondents.
The SOCIETY OF the PLASTICS INDUSTRY, INC., Petitioner,
v.
Donald KENNEDY, as Commissioner of Food and Drugs, and
Joseph A. Califano, Jr., as Secretary of Health,
Education and Welfare, Respondents.
VISTRON CORPORATION, Petitioner,
v.
Joseph A. CALIFANO, as Secretary of Health, Education and
Welfare and Donald Kennedy, as Commissioner of
Food and Drugs, Respondents.
The CONTINENTAL GROUP, INC., Petitioner,
v.
Donald KENNEDY, Commissioner of Food and Drugs, Respondent.
Nos. 77-2023, 77-2024, 77-2026 and 77-2032.
United States Court of Appeals,
District of Columbia Circuit.
Argued March 15, 1979.
Decided Nov. 6, 1979.

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John H. Pickering, Washington, D. C., with whom Jerome H. Heckman, William T. Lake and Michael S. Schooler, Washington, D. C., were on the brief, for petitioner in No. 77-2023.

Joel E. Hoffman, Washington, D. C., with whom Gloria Phraes Stewart, Washington, D. C., was on the brief, for petitioner in No. 77-2032.

Edward B. Williams, Washington, D. C., with whom John F. Jones, Cleveland, Ohio, George Meader and Daniel S. Orci, Jr., Washington, D. C., were on the brief, for petitioner in No. 77-2026.

Jerome H. Heckman, Washington, D. C., with whom John B. Dubeck and John S. Eldred, Washington, D. C., were on the brief, for petitioner in No. 77-2024.

Richard M. Cooper, Chief Counsel, Food and Drug Administration, Rockville, Md., with whom Charles R. McConachie, J. Patrick Glynn, Attys., Dept. of Justice, and Thomas Scarlett, Attys., Food and Drug Administration, Washington, D. C., were on the brief, for respondents.

Marcia J. Cleveland, New York City, was on the brief, for Amicus curiae, Natural Resources Defense Council, Inc. urging affirmance.

Eugene I. Lambert, Allan J. Topol and Richard F. Kingham, Washington, D. C., were on the brief, for amicus curiae, American Can Co. et al., urging that the Commission's order to be set aside with directions to reinstate the regulations.

Malcolm D. MacArthur, Washington, D. C., was on the brief, for amicus curiae, National Flexible Packaging Ass'n urging Commissioner's order to be vacated and set aside.

Ronald A. Zumbrun, Robert K. Best, Raymond M. Momboisse, Sacramento, Cal., Albert Ferri, Jr. and Donald C. Simpson were on the brief, for Amicus Curiae, Pacific Legal Foundation, Washington D.C., urging the order be reversed and vacated.

Before BAZELON, Senior Circuit Judge, and LEVENTHAL and ROBINSON, Circuit Judges.

Opinion for the Court filed by Circuit Judge LEVENTHAL.

LEVENTHAL, Circuit Judge:

This case arises on a petition for review of a Final Decision and Order of the Commissioner of Food and Drugs 1 in which he ruled that a substance used to fabricate unbreakable beverage containers, acrylonitrile copolymer, is a "food additive" within the meaning of section 201(s) of the Federal Food, Drug, and Cosmetic Act (the Act). 2 He further concluded that the data of record failed to provide the demonstration of safety established by section 409(c)(3) (A) of the Act as a precedent to FDA approval for

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use of any "food additive." 3 The Commissioner's Final Order amended the pertinent FDA regulations to provide: "Acrylonitrile copolymers (of the type identified in the regulations) are not authorized to be used to fabricate beverage containers." 4

For the reasons set forth below, the decision of the Commissioner is affirmed in part, and in part is remanded to provide the opportunity for reconsideration.

I.

The FDA determination that acrylonitrile copolymers used in beverage containers are "food additives" within the statute is based on the finding that such containers invariably retain a residual level of acrylonitrile monomer that has failed to polymerize completely during the manufacturing process and that will migrate from the wall of the container into the beverage under the conditions of intended use. Although the administrative proceedings focused on beverage containers with a residual acrylonitrile monomer (RAN) level equal to or greater than 3.3 parts per million (ppm), the Commissioner made findings and conclusions applicable to all beverage containers manufactured with acrylonitrile, and the Final Order prohibited manufacture of such containers irrespective of their RAN levels. 5

FDA began to focus on acrylonitrile copolymer beverage containers in 1974, when the duPont Company submitted test results on a container fabricated from a somewhat different substance which alerted FDA to the possibility of significant migration from acrylonitrile containers. Subsequently, the Commissioner determined that, because of this putative migration, acrylonitrile copolymer was a "food additive" within the statute, and, on February 12, 1975, he published a regulation prescribing the conditions under which the chemical might be used safely in beverage containers: RAN levels in the wall of the container were limited to 80 parts per million (ppm), and acceptable migration of acrylonitrile monomer into the food was set at 300 ppb (parts per billion). 6

Two years later, FDA issued test results indicating that acrylonitrile caused adverse

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affects in laboratory animals. The Commissioner announced that he would lower the acceptable migration threshold for nonbeverage containers to 50 ppb, and would withdraw approval entirely for acrylonitrile beverage containers, on the

assumption that no such container could satisfy the 50 ppb migration limitation. 7 Upon judicial review, this court held FDA's suspension of its food additive regulation without a hearing to be invalid. The court stayed the administrative action on March 18, 1977 8 and ordered that the required hearing be completed within 60 days. Monsanto Co. v. Gardner (No. 77-1245, 3/18/77). Subsequently, on a joint motion of the parties, the time limitation was extended by 120 days.

At the administrative hearing, petitioners introduced results from tests on a newly developed acrylonitrile beverage container having a RAN level of approximately 3.3 ppm. Tests on the container, employing a detection method sensitive to 10 ppb, detected no migration of acrylonitrile monomer. Nevertheless, the administrative law judge found that acrylonitrile copolymer was a "food additive," since migration had been detected from beverage containers composed of the same chemical compounds, though with higher RAN levels than those present in the "new" container. 9 The Final Order prohibited manufacture of beverage containers containing acrylonitrile copolymer irrespective of their RAN levels. 10

II.

This case brings into court the second law of thermodynamics, which C. P. Snow used as a paradigm of technical information well understood by all scientists and practically no persons of the culture of humanism and letters. 11 That law leads to a scientifically indisputable prediction that there will be Some migration of Any two substances which come in contact. The Commissioner's Final Decision, which upheld the ALJ's determination, is unclear on whether and to what extent reliance was placed on this "diffusion principle" rather than on a meaningful projection from reliable data. At one point in the Final Decision the Commissioner stated: "the migration of any amount of a substance is sufficient to make it a food additive" 12 a passage evocative of the diffusion principle. Elsewhere, the Commissioner stated that he was able to make a finding of migration based on a projection from actual data on the assumption that a roughly linear relationship (as a function of time and temperature) existed between the RAN levels in a container and the concentration of acrylonitrile that would migrate into a test fluid. On this premise, though migration from the 3.3 ppm RAN container was itself below the threshold of detectability (10 ppb), it could be projected from the testing data obtained from containers with higher RAN levels. 13

This was a troublesome aspect of the case. As it was presented to us, the Commissioner had made a projection of migration from 3.3 ppm RAN containers without the support of any actual data showing that migration had occurred from such containers. One of petitioners' experts put it that the relationship might not be linear at very low RAN levels; but this was dismissed by the Commissioner as "speculative." 14 One

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could not say that the expert's contention of no migration from very low RAN containers was improbable as a concept of physical chemistry, but it was put to us that the validity of this contention could neither be demonstrated nor refuted for 3.3 ppm RAN containers because, under the conditions of intended use, migration was projected to occur in amounts below the threshold of detectability.

Our own study showed the possibility of using experimental data to check the FDA's projection analysis. The FDA revealed that a projection of migration from low RAN containers had in fact been made for test conditions of prolonged duration and above-normal temperature. Under such conditions migration was projected in concentrations greater than 10 ppb, the threshold of detectability at the time of the Final Decision. 15 Therefore, this court requested post-argument memoranda from the parties on whether tests had been performed, or would be feasible, to confirm by actual data the hypothesis that migration occurs from containers with a RAN level of 3.3 ppm.

The responses to our inquiry have revealed the probable existence of data unavailable to counsel during the administrative proceedings that bear importantly upon the assumptions made by the Commissioner in reaching his findings and conclusions. This discovery buttressed our earlier conclusion that the Commissioner did not have sufficient support for his decision to apply the "food additive" definition in this case.

In light of the inadequacy of the agency's inquiry and in light of our view that the Commissioner has a greater measure of discretion in applying the statutory definitions of "food additive" than he appears to have thought, we remand this proceeding for further consideration.

III

The proceedings at hand are dramatic testimony to the rapid advance of scientific knowledge in our society. At the time of the administrative proceedings, the lowest concentration of acrylonitrile in a test fluid that could be detected with an acceptable degree of confidence was 10 ppb. There are now analytical techniques available that can detect acrylonitrile concentration of 0.1 ppb, an improvement of two orders of magnitude. 16 Thus, on the issue of migration of acrylonitrile monomer it is now possible to generate "hard" data previously unobtainable.

In his post-argument testimony, Monsanto's expert claims, on the basis of such "hard" data, that the hypothesis which the Commissioner labeled as "speculative" may accurately describe the migration characteristics of containers with very low RAN levels, to wit, that in such containers the acrylonitrile monomer is so firmly affixed within the structure of the copolymer that no migration will occur under the conditions of intended use. 17 If these assertions can be demonstrated to the satisfaction of the Commissioner, a modification of the current regulation is a likely corollary. The actual issuance of a regulation approving the production of a beverage container with an acceptable RAN level would presumably require both a container that had been developed 18 and the appropriate petition. How

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ever, the Commissioner would have latitude to issue a statement of policy based upon the results of the proceeding or remand that would specify what in his review was an acceptable RAN level. This would serve a technology-forcing objective. 19

FDA opposes petitioners' post-argument motion for remand, asserting that the proffered new evidence will not affect the Commissioner's order insofar as that order precludes manufacture of beverage containers with RAN levels equal to or greater than 3.3 ppm the type of container already tested. FDA points out that the material submitted in response to this court's inquiry affirmatively supports the validity of the Commissioner's findings and conclusions. 20 FDA contends that a petition for modification of the regulation, or a similar procedure, would be the appropriate vehicle for presentation of any new evidence indicating that migration ceases when RAN levels fall below a certain threshold.

As a general rule, courts defer to administrative agency orders closing the record and terminating proceedings. The rule has applicability in cases involving scientific matters notwithstanding the possibility that advances and experiments will yield new material data. Indeed, the importance of finality as a matter of administrative necessity may be magnified by the possibility indeed probability of advance in at least some areas. Procedures for rehearing or modifying orders are generally available to provide appropriate relief from any hardships or other harm. 21

The general rule of finality applies in the usual case because the courts trust the administrator's ability to make a reasoned judgment that sufficient evidence has been submitted, that adequate time has been provided for rebuttal, and that the record should be closed.

However, in this instance, the closing of the record did not reflect unfettered administrative judgment: FDA conducted these administrative proceedings under a time constraint dictated by an order of this court.

The Court is also concerned that the Commissioner may have reached his determination in the belief that he was constrained to apply the strictly literal terms of the statute irrespective of the public health and safety considerations. As we discuss below, there is latitude inherent in the statutory scheme to avoid literal application of the statutory definition of "food additive" in those De minimis situations that, in the informed judgment of the Commissioner, clearly present no public health or safety concerns.

In the usual case, the general doctrine of necessity and finality serves the public interest in immediate protection of the consuming public. But in this case production of acrylonitrile beverage containers was deferred voluntarily even when this court issued a stay of the FDA order, and in any event it is now prohibited pending further proceedings.

Finally, we are concerned that the record reflects a momentum toward a precipitate determination. Several factors bear on our judgment. One is the text of the decision, with its lack of precision as to basis. Another is the fact that the beverage container evaluated by the Commissioner was characterized by a migration level well below the agency's initial limit. It was offered by

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petitioners in the hearing as available as a result of ongoing technology, but the time constraint imposed by judicial mandate prevented the agency from scheduling the kind of administrative consideration that would ordinarily have been provided.

IV

Pretermitting various issues that should await conclusion of the remand proceedings, we turn to certain other important questions that are presented by the record, that have been fully briefed and argued, and that are ripe for resolution. 22

The statute requires a demonstration of safety precedent to FDA approval of any "food additive." 23 The statutory definition of "food additive" which triggers that requirement contains a two part test. First, the Component element of the definition states that the intended use of the substance must be reasonably expected to result in its becoming a component of any food. 24 Second, the Safety element of the definition states that the substance must be not "Generally recognized (as) safe under the conditions of its intended use." 25

Petitioners are concerned that the Commissioner has determined, or will determine, that the component element of the definition may be satisfied solely by that application of the second law of thermodynamics called the diffusion principle: Any two substances that are in contact will tend to diffuse into each other at a rate that will be determined as a function of time, temperature, and the nature of the substances. Congress did not intend that the component requirement of a "food additive" would be satisfied by a mere recitation of the diffusion principle, a mere finding of any contact whatever with food. Petitioner's contention on this point is sound.

For the component element of the definition to be satisfied, Congress must have intended the Commissioner to determine with a fair degree of confidence that a substance migrates into food in more than insignificant amounts. We do not suggest that the substance must be toxicologically significant; that aspect is subsumed by the safety element of the definition. Nor is it necessary that the level of migration be significant with reference to the threshold of direct detectability, so long as its presence in food can be predicted on the basis of a meaningful projection from reliable data. Congress has granted to the Commissioner a

limited but important area of discretion. Although as a matter of theory the statutory net might sweep within the term "food additive" a single molecule of any substance that finds its way into food, the Commissioner is not required to determine that the component element of the definition has been satisfied by such an exiguous showing. The Commissioner has latitude under particular circumstances to find migration "insignificant" even giving full weight to the public health and welfare concerns that must inform his discretion.

Thus, the Commissioner may determine based on the evidence before him that the level of migration into food of a particular chemical is so negligible as to present no public health or safety concerns, even to assure a wide margin of safety. This authority derives from the administrative discretion, inherent in the statutory scheme, to deal appropriately with De minimis situations. 26 However, if the Commissioner

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declines to define a substance as a "food additive," though it comes within the strictly literal terms of the statutory definition, he must state the reasons for exercising this limited exemption authority. In context, a decision to apply the literal terms of the statute, requires nothing more than a finding that the elements of the "food additive" definition have been satisfied. 27

In the case at hand, the Commissioner made specific rulings that the component element of the definition was satisfied with respect to acrylonitrile beverage containers having an RAN level of 3.3 ppm or more. These rulings were premised on a projection, based on an extrapolation from reliable data, of migration of acrylonitrile monomer in then-undetectable amounts. In light of the supplementary submission made in response to the post-argument inquiry of this court, we find that the determination can be made for the 3.3 ppm RAN containers with an appropriate degree of confidence, and with the support of the required quantum of evidence. 28

Turning to the safety element of the definition, the Commissioner determined that the scientific community had insufficient experience with acrylonitrile to form a judgment as to safety. Based on this lack of opinion, the Commissioner made a finding that acrylonitrile was not generally recognized as safe within the meaning of the statute. The Commissioner acted within his discretion in making such a finding, but we note that the underlying premise may be affected, perhaps weakened, perhaps strengthened, with time and greater experience with acrylonitrile. 29 This finding on the safety element will be open to reexamination on remand at the discretion of the Commissioner. He would have latitude to consider whether acrylonitrile is generally recognized as safe at concentrations below a certain threshold, even though he has determined for higher concentrations that in the view of the scientific community acrylonitrile is not generally recognized as safe.

V

Petitioners also made a claim of discriminatory treatment that the Commissioner is applying policies in the petitioners' case that have not been applied in other similar circumstances. However, there is no claim that the Commissioner was motivated by discriminatory intention to bring the petitioners before the agency and to focus on their product. Petitioners came before the agency in the ordinary course. Once the Commissioner undertook scrutiny, he shifted the lens of his microscope to a higher power but that is no ground for objection, so long as the final action remains within the legitimate scope of discretion.

The decision of the Commissioner is affirmed in part, and in part is remanded to provide the opportunity for reconsideration.

So ordered.

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1 Acrylonitrile Copolymers Used to Fabricate Beverage Containers, Final Decision, 42 Fed.Reg. 48528-48544 (1977); J.A. at 1-17.

2 Id., Conclusion of Law P 15, 42 Fed.Reg. at 48543; J.A. at 16. Section 201(s) of the Act, 21 U.S.C. § 321(s) (1976) provides:

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case as a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

(4) any substance used in accordance with a sanction or approval granted prior to September 6, 1953, pursuant to this chapter, the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) or the Meat Inspection Act of March 4, 1907, as amended and extended (21 U.S.C. 601 et seq.); or

(5) a new animal drug.

3 Final Decision, note 1 Supra, Conclusions of Law P 16, 42 Fed.Reg. at 48543; J.A. at 16. Section 409(c), 21 U.S.C. § 348(c) (1976), provides in part:

(c) Approval or denial of petition; time for issuance of orders; evaluation of data; factors

(1) The Secretary shall

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1)(A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such

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regulation shall issue if a fair evaluation of the data before the Secretary

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: . . .

4 Final Decision, note 1 Supra, Final Order, 42 Fed.Reg. at 48543-44; J.A. 16-17. The provisions of the Order have been incorporated into FDA regulations at 21 C.F.R. §§ 177.1020(f), 177.1030(f), 177.1040(e), 177.1050(g) and 177.1480(d) (1978).

5 See e. g., 21 C.F.R. § 177.1040(c) (1978). This is the regulation under which petitioner Monsanto manufactures its acrylonitrile beverage container. Petitioner Vistron's container is manufactured under 21 C.F.R. § 177.1480 (1978).

6 40 Fed.Reg. 6489 (1975); J.A. at 22.

7 42 Fed.Reg. 13540 (1977); J.A. at 139.

8 Monsanto Br. at 17 states that there has been no use of the court's stay to continue manufacture.

9 Acrylonitrile Copolymers Used To Fabricate Beverage Containers, Initial Decision 35 (August 4, 1977); J.A. at 186.

10 See, e. g., 21 C.F.R. § 177.1040(c) (1978). This is the regulation under which petitioner Monsanto manufactures its acrylonitrile beverage container. Petitioner Vistron's container is manufactured under 21 C.F.R. § 277.1480 (1978).

11 See C. P. Snow, The Two Cultures and the Scientific Revolution (1959).

12 Final Decision, note 1 Supra, 42 Fed.Reg. at 48534; J.A. at 7. Id., 42 Fed.Reg. at 48532-33; J.A. at 5-6.

13 Id., 42 Fed.Reg. at 48529-48530; J.A. at 2-3.

14 The suggestion was made in the prepared testimony of Monsanto's expert witness, Mr. Morris Salame. J.A. at 457-58. The Commissioner dismissed the hypothesis as "speculative" in his response to the exceptions of the parties. Final Decision, note 1 Supra, part C(2)(a)(i), 42 Fed.Reg. at 48530-31; J.A. at 3-4.

15 The chart showed the following projections of migration from a beverage container with a RAN level of 3.7 ppm:

at 150 degrees F for 30 days --26 ppb;

at 120 degrees F for 180 days --27 ppb;

at 120 degrees F for 90 days --14 ppb.

J.A. at 794.

16 Memorandum of Monsanto Company In Support of Motion For Remand Under Section 409(g)(4) at 4.

17 Affidavit of Morris Salame, accompanying Monsanto Memorandum, note 16 Supra, at PP 9, 10.

18 The Act does not contemplate promulgation of food additive regulations for hypothetical food additives. 21 U.S.C. §§ 321(s) & 348(c) (1976). The Commissioner must base his decision on a container actually existing and actually before him in the remand proceeding or any subsequent proceeding.

19 The submission by Monsanto is that no migration can be expected to occur from containers with RAN levels lower than 0.1 ppm. Salame Affidavit, note 16 Supra, at P 10. There is a further indication that the manufacture of beverage containers with RAN levels of less than 0.1 ppm is technologically feasible. Monsanto Memorandum, note 15 Supra, at 7.

20 In view of the new data generated in response to the Court's inquiry, petitioners no longer contest that migration does occur from Monsanto's "Cycle-Safe" container (RAN level of 3.3 ppm) under the conditions of its intended use. See Salame Affidavit, note 16 Supra ; Monsanto Memorandum, note 15 Supra, at 11.

21 See Investment Co. Institute v. Federal Reserve System, 179 U.S.App.D.C. 311, 322, 551 F.2d 1270, 1281 (1977).

22 The issues fully ripe for decision at this time include questions of statutory interpretation that will be pertinent to the proceeding on remand.

23 See § 409(c)(3)(A), quoted in note 3, Supra.

24 See note 2 Supra.

25 Id.

26 See, e. g., FPC v. Texaco, Inc., 417 U.S. 380, 399, 94 S.Ct. 2315, 41 L.Ed.2d 141 (1974); Volkswagenwerk, A. G. v. FMC, 390 U.S. 261, 276-77, 88 S.Ct. 929, 19 L.Ed.2d 1090 (1968); United Glass & Ceramic Workers v. Marshall, 189 U.S.App.D.C. 240, 242, 584 F.2d 398, 400 (1978); Marine Space Enclosures, Inc. v. FMC, 137 U.S.App.D.C. 9, 16, 420 F.2d 577, 584 (1969). Cf. Ingraham v. Wright, 430 U.S. 651, 674, 97 S.Ct. 1401, 51 L.Ed.2d 711 (1977). Sniadach v. Family Finance Corp., 395 U.S. 337, 342, 89 S.Ct. 1820, 23 L.Ed.2d 349 (1969) (Harlan, J., concurring).

27 Absent a showing of bad faith or other extraordinary circumstances, a court will not consider meritorious the claim that the Commissioner has abused his discretion in declining to exercise his exemption authority for De minimis situations. This is an area of decision by its nature committed to the informed discretion of the Commissioner.

28 See note 20 Supra. On judicial review, the court must be satisfied that the Order of the Commissioner is based "upon a fair evaluation of the entire record." 21 U.S.C. § 348(f)(2), (g)(3) (1976). The Commissioner applied the "component" part too automatically, and in the future must support his decision with more than a conclusory reference to the diffusion principle of the second law of thermodynamics.

29 Like the "component" element of the definition, the "safety" element may at times call for more rigorous examination. Thus, the Commissioner has discretion in determining when the statute applies to a given substance, but substances that do fall within its term should be so identified.