United States of America v. Nova Scotia Food Products Corporation

568 F.2d 240 (2d Cir. 1977)

[Judge Gurfein] This appeal involving a regulation of the Food and Drug Administration is not here upon a direct review of agency action. It is an appeal from a judgment of the District Court for the Eastern District of New York * * * enjoining the appellants, after a hearing, from processing hot smoked whitefish except in accordance with time-temperature-salinity (T-T-S) regulations contained in 21 C.F.R. Part 122 (1977). * * * The injunction was sought and granted on the ground that smoked whitefish which has been processed in violation of the T-T-S regulation is "adulterated."

Appellant Nova Scotia receives frozen or iced whitefish in interstate commerce which it processes by brining, smoking and cooking. The fish are then sold as smoked whitefish. The regulations cited above require that hot-process smoked fish be heated by a controlled heat process that provides a monitoring system positioned in as many strategic locations in the oven as necessary to assure a continuous temperature through each fish of not less than 180o F. for a minimum of 30 minutes for fish which have been brined to contain 3.5% Water phase salt or at 150o F. for a minimum of 30 minutes if the salinity was at 5% Water phase. Since each fish must meet these requirements, it is necessary to heat an entire batch of fish to even higher temperatures so that the lowest temperature for *any* fish will meet the minimum requirements.

Government inspection of appellants' plant established without question that the minimum T-T-S requirements were not being met. There is no substantial claim that the plant was processing whitefish under "insanitary conditions" in any other material respect. * * * The hazard which the FDA sought to minimize was the outgrowth and toxin formation of Clostridium botulinum Type E spores * * * These bacteria can * * * invade fish in their natural habitat and can be further disseminated in the course of evisceration and preparation of the fish for cooking. A failure to destroy such spores through an adequate brining, thermal, and refrigeration process was found to be dangerous to public health.

The Commissioner of Food and Drugs ("Commissioner"), employing informal "notice-and-comment" procedures under 21 U.S.C. § 371(a), issued a proposal for the control of C. botulinum bacteria Type E in fish. For his statutory authority to promulgate the regulations, the Commissioner specifically relied only upon § 342(a) (4) of the Act which provides:

> "A food shall be deemed to be adulterated - * * *
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> "(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;"

Similar guidelines for smoking fish had been suggested by the FDA several years earlier, and were generally made known to people in the industry. At that stage, however, they were merely guidelines without substantive effect as law. Responding to the Commissioner's invitation in the notice of proposed rulemaking, members of the industry, including appellants and the intervenor-appellant, submitted comments on the proposed regulation. * * *

The intervenor [National Fisheries Institute, Inc.] suggested that "specific parameters" be established. This referred to particular processing parameters for different species of fish on a "species by species" basis. Such "species by species" determination was proposed not only by the intervenor but also by the Bureau of Commercial Fisheries of the Department of the Interior. That Bureau objected to the general application of the T-T-S requirement proposed by the FDA on the ground that application of the regulation to all species of fish being smoked was not commercially feasible, and that the regulation should therefore specify time-temperature-salinity requirements, as developed by research and study, on a species-by-species basis. The Bureau suggested that "wholesomeness considerations could be more practically and adequately realized by reducing processing temperature and using suitable concentrations of nitrite and salt." The Commissioner took cognizance of the suggestion, but decided, nevertheless, to impose the T-T-S requirement on all species of fish (except chub, which were [separately] regulated * * *)

[The Commissioner acknowledged] in his "basis and purpose" statement required by the Administrative Procedure Act ("APA"), 5 U.S.C. § 553(c), that "adequate times, temperatures and salt concentrations have not been demonstrated for each individual species of fish presently smoked." The Commissioner concluded, nevertheless, that "the processing requirements of the proposed regulations are the safest now known to prevent the outgrowth and toxin formation of *C. botulinum Type E*". He determined that "the conditions of current good manufacturing practice for this industry should be established without further delay."

The Commissioner did not answer the suggestion by the Bureau of Fisheries that nitrite and salt as additives could safely lower the high temperature otherwise required, a solution which the FDA had accepted in the case of chub. Nor did the Commissioner respond to the claim of Nova Scotia through its trade association, the Association of Smoked Fish Processors, Inc., Technical Center that "(t)he proposed process requirements suggested by the FDA for hot processed smoked fish are neither commercially feasible nor based on sound scientific evidence obtained with the variety of smoked fish products to be included under this regulation." Nova Scotia, in its own comment, wrote to the Commissioner that "the heating of certain types of fish to high temperatures will completely destroy the product". It suggested, as an alternative, that "specific processing procedures could be established for each species after adequate work and [experimentation] has been done but not before." * * *

When, after several inspections and warnings, Nova Scotia failed to comply with the regulation, an action by the United States Attorney for injunctive relief * * * resulted in the judgment here on appeal. * * * The key issues were (1) whether, in the light of the rather scant history of botulism in whitefish, that species should have been considered separately rather than included in a general regulation which failed to distinguish species from species; (2) whether the application of the proposed T-T-S requirements to smoked whitefish made the whitefish commercially unsaleable; and (3) whether the agency recognized that prospect, but nevertheless decided that the public health needs should prevail even if that meant commercial death for the whitefish industry. The procedural issues were whether, in the light of these key questions, the agency procedure was inadequate because (i) it failed to disclose to interested parties the scientific data and the methodology upon which it relied; and (ii) because it failed utterly to address itself to the pertinent question of commercial feasibility.

1. The History of Botulism in Whitefish

The history of botulism occurrence in whitefish, as established in the trial record, which we must assume was available to the FDA in 1970, is as follows. Between 1899 and 1964 there were only eight cases of

botulism reported as attributable to hot-smoked whitefish. In all eight instances, vacuum-packed whitefish was involved. * * * The industry has abandoned vacuum-packing, and there has not been a single case of botulism associated with commercially prepared whitefish since 1963, though 2,750,000 pounds of whitefish are processed annually. Thus, in the seven-year period from 1964 through 1970, 17.25 million pounds of whitefish have been commercially processed in the United States without a single reported case of botulism. The evidence also disclosed that defendant Nova Scotia has been in business some 56 years, and that there has never been a case of botulism illness from the whitefish processed by it.

2. The Scientific Data

Interested parties were not informed of the scientific data, or at least of a selection of such data deemed important by the agency, so that comments could be addressed to the data. Appellants argue that unless the scientific data relied upon by the agency are spread upon the public records, criticism of the methodology used or the meaning to be inferred from the data is rendered impossible.

We agree with appellants in this case, for although we recognize that an agency may resort to its own expertise outside the record in an informal rulemaking procedure, we do not believe that when the pertinent research material is readily available and the agency has no special expertise on the precise parameters involved, there is any reason to conceal the scientific data relied upon from the interested parties. * * * This is not a case where the agency methodology was based on material supplied by the interested parties themselves. Here all the scientific research was collected by the agency, and none of it was disclosed to interested parties as the material upon which the proposed rule would be fashioned. Nor was an articulate effort made to connect the scientific requirements to available technology that would make commercial survival possible, though the burden of proof was on the agency. This required it to "bear a burden of adducing a reasoned presentation supporting the reliability of its methodology."

If the failure to notify interested persons of the scientific research upon which the agency was relying actually prevented the presentation of relevant comment, the agency may be held not to have considered all "the relevant factors." We can think of no sound reasons for secrecy or reluctance to expose to public view (with an exception for trade secrets or national security) the ingredients of the deliberative process. Indeed, the FDA's own regulations now specifically require that every notice of proposed rulemaking contain "references to all data and information on which the Commissioner relies for the proposal * * * And this is, undoubtedly, the trend.

We think that the scientific data should have been disclosed to focus on the proper interpretation of "insanitary conditions." * * * One cannot ask for comment on a scientific paper without allowing the participants to read the paper. Scientific research is sometimes rejected for diverse inadequacies of methodology; and statistical results are sometimes rebutted because of a lack of adequate gathering technique or of supportable extrapolation. Such is the stuff of scientific debate. To suppress meaningful comment by failure to disclose the basic data relied upon is akin to rejecting comment altogether. * * * [W]e conclude that the failure to disclose to interested persons the scientific data upon which the FDA relied was procedurally erroneous. Moreover, the burden was upon the agency to articulate rationally why the rule should apply to a large and diverse class, with the same T-T-S parameters made applicable to *all* species.

Appellants additionally attack the "concise general statement" required by APA, 5 U.S.C. § 553, as inadequate. We think that, in the circumstances, it was less than adequate. It is not in keeping with the rational process to leave vital questions, raised by comments which are of cogent materiality, completely unanswered. The agencies certainly have a good deal of discretion in expressing the basis of a rule, but the agencies do not have quite the prerogative of obscurantism reserved to legislatures. The test of adequacy of the "concise general statement" was expressed by Judge McGowan in the following terms: * * * [T]he 'concise general statement of . . . basis and purpose' * * * will enable us to see what major issues of policy were ventilated by the informal proceedings and why the agency reacted to them as it did." * * *

The Secretary was squarely faced with the question whether it was necessary to formulate a rule with specific parameters that applied to all species of fish, and particularly whether lower temperatures with the addition of nitrite and salt would not be sufficient. Though this alternative was suggested by an agency of the federal government, its suggestion, though acknowledged, was never answered.

Moreover, the comment that to apply the proposed T-T-S requirements to whitefish would destroy the commercial product was neither discussed nor answered. We think that to sanction silence in the face of such vital questions would be to make the statutory requirement of a "concise general statement" less than an adequate safeguard against arbitrary decision-making. * * * One may recognize that even commercial infeasibility cannot stand in the way of an overwhelming public interest. Yet the administrative process should disclose, at least, whether the proposed regulation is considered to be commercially feasible, or whether other considerations prevail even if commercial infeasibility is acknowledged. This kind of forthright disclosure and basic statement was lacking * * * It is easy enough for an administrator to ban everything. In the regulation of food processing, the worldwide need for food also must be taken into account in formulating measures taken for the protection of health. * * *

When the District Court held the regulation to be valid, it properly exercised its discretion to grant the injunction. In view of our conclusion to the contrary, we must reverse the grant of the injunction and direct that the complaint be dismissed.