A failure to coordinate more effectively has prevented FDA from testing the USDA method. FDA had asked for more information on the test. However, red-tape delays, and a failure to publish the Banwart findings in a scientific journal apparently has held up an exchange of information on the subject.

FDA's field laboratories have been tied up in knots working on Salmonella samples, and an improved method most certainly would cut down the workload. FDA scientists recently held a workshop designed to aid in the development of the fluorescent-antibody method of Salmonella detection (See FOOD CHEMICAL NEWS, June 19, Page 15).

FDA has apparently concluded that this method would not solve its regulatory problems, since it is not foolproof. However, work is expected to continue on the fluorescent-antibody method as an aid to industry in its efforts to combat Salmonella contamination.

FDA recently signed a $64,000 contract with the National Academy of Sciences to evaluate Salmonella problems and another for $60,000 with the Midwest Research Institute, Kansas City, Mo., to help develop systems analyses for combatting Salmonella problems.

USDA's screening test, now being tested commercially, the Department said would save laboratory space, labor and shipping delays. USDA requires pasteurization of all egg products produced under inspection and moving in interstate commerce. Tests still must be made, however, to check for inefficient pasteurization or post-pasteurization contamination.

The present commercial test procedure, which is also utilized by FDA, requires 3 steps, each taking 24 hours or more and totalling from 72 to 96 hours. Banwart's test shortens the time considerably, determining samples that are Salmonella negative. Samples showing a positive reaction must be tested further under conventional methods to determine specifically whether Salmonella or other organisms are present.

In a 42-hour period, Banwart tested 225 samples of dried whole egg with the new method and found 145 without Salmonella. Using the conventional method, it took him 90 hours to find 118 samples without Salmonella. Further testing of the presumptive samples showed 8 actually contained Salmonella organisms.

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GOODRICH INTERPRETS SCOTUS DECISIONS ON PRE-ENFORCEMENT REVIEW

The decision to review or not to review Food and Drug Administration rule-making actions before they are put into force was left "largely discretionary" by the Supreme Court, according to William W. Goodrich, Health, Education and Welfare Assistant General Counsel for FDA.

Addressing the American Bar Association's Food, Drug, and Cosmetic Division in Honolulu Aug. 2, Goodrich gave his view of the meaning of the recent Supreme Court decisions granting the Toilet Goods Association and the Pharmaceutical Manufacturers Association pre-enforcement judicial review of FDA regulations (See FOOD CHEMICAL NEWS, May 29, Page 3).

He conceded only that the decisions laid to rest any question of judicial power to entertain suits for pre-enforcement review.

"Where Section 701(e), the statutory review procedure, applies," Goodrich explained, "we believe that will continue as the required route for the challenger," and he cited the ruling of the Court of Appeals in the District of Columbia denying the dietary food supplement appeal by PMA as justification for this belief (See FOOD CHEMICAL NEWS, June 26, Page 10). He continued:

> "But otherwise it appears that the Courts will entertain a pre-enforcement challenge only when there is a great hardship on private parties in withholding court consideration and when the cases present essentially legal issues that are ripe for judicial resolution without an evidentiary trial or administrative hearing."

Goodrich asked what makes an issue fit for judicial decision, and answered:

> "First, the interpretive regulations must be issued after notice and an opportunity for comment, as provided in the Administrative Procedure Act, and must carry no hint of informality. This is 'final agency action' within the meaning of the Administrative Procedure Act. Such regulations, if authorized by the Federal Food, Drug, and Cosmetic Act, the Court said have the status of law and violations carry criminal and civil sanctions. Their immediate legal impact makes them reviewable.
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> "Second, they must present a purely legal question of statutory construction in terms of Congressional intent or statutory language, and must not involve factual matters that require Agency resolution. The Supreme Court said that if, at an evidentiary hearing, the District Court is persuaded that technical questions are raised that require a more concrete setting for proper adjudication, such as would arise in an actual enforcement proceeding, a pre-enforcement order should not issue."

Once the issue is found to be fit, the FDA legal counsel said, the District Court is then to decide the question of hardship which will arise if early judicial relief is denied.

"Here, the most important consideration is the impact of the regulation," he continued, asking: "Does the regulation have an immediate, direct and legally binding impact upon the day-to-day business affairs of the affected industry?"

Noting that primary conduct must be affected, Goodrich suggested that the regulation "must cause the industry, for example, to test or substitute ingredients now - - not perhaps, not in the future - - now."

He noted that the Supreme Court found it particularly relevant that the plaintiffs challenging the interpretive regulations represented nearly all - - 90% - - of the affected industries.

"If there is a substantial governmental interest against judicial inquiry in a pre-enforcement setting," he declared, "that interest is to be protected," and he added:

> "Relief can be denied on the ground that there is a multiplicity of suits for harrassment purposes. And those regulated cannot sit idly by with the intent to institute a suit to review the regulation sometime in the future 'in case things get hot.' The Court specifically pointed out that the defense of laches is available to the Government.
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> "Finally, even if a suit is instituted and the Court decides to hear the case, that is not an automatic stay of the application of the regulation. The burden is on the applicant to allege and establish the necessity for the stay along the traditional lines."

Goodrich concluded that the SCOTUS decisions "do not provide automatic access to the Courts, but they do grant the District Courts power to review some interpretive regulations issued as the final action of the FDA."

"Informal advisory opinions, even by the Commissioner, as well as rulings of subordinate officials, and tentative regulations," he stated as his view, "remain non-reviewable as always."

Goodrich told the ABA meeting that the initial food industry reaction to the agency's finalized FPLA regulations indicates that a contest "is not likely." He said the regulations are subject to objection and public proceedings on any objection that may be filed, adding that it is possible that their effective dates may be thus delayed.

Looking ahead, he said the drug and cosmetic FPLA mandatory regulations will soon be issued, as well as the beginning programs on the discretionary regulations, including "regulations making exemptions, regulations for cents-off and other bargain promotions, regulations to prevent non-functional slack filling of containers, regulations for 'large,' 'small,' and 'king' size containers, and regulations requiring additional ingredient information in the labeling of drugs and cosmetics."