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PESTICIDES

The recent decision by the U.S. Court of Appeals for the Fourth Circuit vacating and remanding a biological opinion by the National Marine Fisheries Service regarding registration of three pesticides by the Environmental Protection Agency underscores the difficulty of expeditious review and approval of pesticide products. This article reviews the context and holding of the Fourth Circuit's ruling, the decision's implications, and how they reasonably can be addressed within the context of interagency consultations under the Endangered Species Act.

Fourth Circuit Decision Increases FIFRA-Endangered Species Act Quandary

BY DAVID B. WEINBERG

The Feb. 21 decision by the U.S. Court of Appeals for the Fourth Circuit in *DowAgroSciences LLC v. National Marine Fisheries Service*[1] (*DAS v. NMFS*) underlines the difficulties facing the U.S. Environmental Protection Agency as it works to integrate Endangered Species Act (ESA[2]) consultations into its pesticide registration program. And last month's optimistic new EPA policy on enhancing stakeholder input on that process (Stakeholder Policy[3]), while a step in the right direction, is at best a partial solution to the problem.

The core problem is that the agencies with which EPA is obliged to consult, the National Marine Fisheries Service (NMFS) and the U.S. Fish and Wildlife Service (FWS), are unable to keep up with EPA's routine

[1] *DowAgroSciences LLC v. National Marine Fisheries Service*, 4th. Cir., No. 11-2337, 2/21/13. *See* 37 DEN A-1, 2/25/13.

[2] 16 U.S.C. § 1531 *et seq*.

[3] *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives*, EPA, Docket ID Number: EPA-HQ-OPP-2012-0442. Available at http://op.bna.com/env.nsf/r?Open=fwhe-967m7b. *See also* 62 DEN A-1, 4/1/13.

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flow of consultation requests, as they have readily admitted to Congress.[4] With the Fourth Circuit decision, existing impediments to moving pesticide registration and reregistration decisions promptly, on statutorily set schedules, will only get worse.

However, there are several paths for overcoming these difficulties. If this can be done, the pertinent agencies, or perhaps even Congress itself, can assure that adequate ESA evaluation of the potential implications of pesticide use occurs, and realistic protective steps are taken, while still assuring that the Services have resources to address their many other obligations and farmers are not deprived of the crop protection products so important to producing a safe and plentiful food supply. This article reviews the context and holding of the Fourth Circuit's recent ruling, the decision's implications, and how they reasonably can be addressed.

I. Background

Remarkably, although the Federal Fungicide, Insecticide, and Rodenticide Act has been in place since 1972, *DAS v. NMFS* was the first case in which an appellate court squarely considered the question of whether a Service must document in its response to a request for consultation why the Service rejected substantive scientific criticisms of its analyses.[5] The court held that the Service must do so in order to comply with the Administrative Procedure Act (APA[6]) and allow meaningful judicial review.

FIFRA requires that EPA ''register''—that is, license—every pesticide before it is put on the market. Through registration, EPA specifies steps necessary to protect workers and the environment and mandates that these be set forth on the pesticide's label.[7]

In the last decade or so, considerable attention has focused on EPA's alleged failure to have complied with the ESA in its approvals of the thousands of pesticide products now on the market.[8] Critics have argued that EPA's extensive preregistration ecological analyses and staff expertise, and regular reviews mandated by Congress,[9] are insufficient to assure protection of endangered and threatened species. They also have argued that FIFRA's standard for approving registrations–that ''when used in accordance with widespread and commonly recognized practices'' the registrations ''will not generally cause unreasonable adverse effects on the environment''[10]—is far less stringent than the ESA's mandate that agencies ''insure'' that their actions are ''not likely to jeopardize the continued existence of any endangered species or threatened species'' or destroy ''critical'' habitat.[11]

In addition, the staffs of EPA and the Services have squabbled for decades over the right way to evaluate potential impacts of pesticide registrations on endangered and threatened species and their habitat. Accommodating their different views has proved impossible. At present, a committee established under the aegis of the National Academy of Sciences (NAS) is considering a series of questions jointly presented to it by EPA, the Services and the Department of Agriculture (USDA) in an attempt to overcome those disagreements.[12] Its initial report is due later this month. But one would have to be a considerable optimist to believe it will bring these disputes to an end.

II. The Lead Up to DAS v. NMFS

The current spate of attention to the interrelationships between FIFRA and ESA decision making—and the spark that ultimately led to the *DAS v. NMFS* decision—began with the filing in 2001 of *Washington Toxics Coalition v. EPA* (W.D. Wash., Civ. No. 01-132). That suit alleged that EPA had failed to consult with NMFS, as required by the ESA, about the impacts of hundreds of pesticides on threatened and endangered salmonids (such as salmon and steelhead) in California and Pacific Northwest waterways. *Washington Toxics* resulted in a court ruling and injunction, upheld on appeal, that set a schedule for EPA to consider the salmonid impacts of registrations of products containing 54 pesticide active ingredients in the region, and to initiate consultations with NMFS where there could be an effect on the species.[13] Among the pesticide registrations subject to the order were the insecticides chlorpyrifos, diazinon and malathion.

EPA met its court-ordered obligation, and sought NMFS's views by asking for ''formal consultation.''[14] But NMFS failed to respond in a timely way. As a result, in 2007 the activists sued that agency. The result was a settlement filed with the court on July 31, 2008, in which NMFS agreed to respond to EPA's consultation requests over the next four years.[15]

NMFS's response to consultation requests from another government agency takes the form of a decision document called a ''biological opinion,'' or ''biop.'' The day the 2008 settlement was filed, NMFS sent to EPA a draft biop addressing the potential impacts on pertinent salmonids of the registration of chlorpyrifos, diazinon and malathion.

EPA had requested consultation on those products in 2003, 2002 and 2004, respectively. Since doing so, however, EPA had undertaken routine ''reregistration'' of

[4] NMFS response to questions submitted to the record by the U.S. Department of Commerce, U.S. Department of Agriculture, U.S. Department of the Interior, and U.S. Environmental Protection Agency, *Joint Oversight Hearing before the House Committees on Natural Resources and Agriculture*, 112th Cong. at 23-34 (2011) (2011 Oversight Hearing).

[5] The consultation requirement is set forth in ESA § 7(a)(2); 16 U.S.C. § 1536(a)(2).

[6] 5 U.S.C. § 500 *et seq*.

[7] 7 U.S.C. § 136a.

[8] *See, e.g., Wash. Toxics Coal. v.EPA*, 357 F. Supp. 2d 1266 (W.D. Wash. 2004), *aff'd*, 413 F.3d 1024, 60 ERC 1940 (9th Cir. 2005).

[9] *See, e.g.*, 7 U.S.C. § 136a-1.

[10] 7 U.S.C. § 136a(c)(5)(D).

[11] 16 U.S.C. § 1536(a)(2).

[12] *Ecological Risk Assessment Under FIFRA and ESA*, The National Academies, http://www8.nationalacademies.org/cp/projectview.aspx?key=49396 (last visited Apr. 1, 2013).

[13] *Wash. Toxics Coal.*, 357 F. Supp. 2d 1266.

[14] *See* 50 C.F.R. § 402.02 (''Formal consultation is a process between the Service and the Federal agency that commences with the Federal agency's written request for consultation under section 7(a)(2) of the Act and concludes with the Service's issuance of the biological opinion under section 7(b)(3) of the Act.'').

[15] Stipulated Settlement Agreement and Order of Dismissal, *NW Coal. for Alts. to Pesticides LLC v. NMFS*, No. 07-1791-RSL (W.D. Wash. Aug. 1, 2008), ECF No. 21.

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the products.[16] In this process, the agency requires registrants to update the scientific analyses supporting the finding that all approved uses meet the FIFRA registration standard described above (''not generally cause unreasonable adverse effects''). Quite often, as a result of these reviews EPA convinces registrants to eliminate previously approved uses or change application practices so that use of the products presents fewer environmental, occupational health or food safety concerns.

In the case of chlorpyrifos, diazinon and malathion, reregistration had resulted in major changes in the products' ongoing usage. All homeowner uses of chlorpyrifos had been eliminated, for example, as had many agricultural uses of all three products. In the few years since those changes had been mandated, the volume of diazinon used had dropped by 67 percent, and similar (albeit not quite as large) reductions had occurred in usage of the other two products.

But NMFS's draft biop made no mention of these changes. Instead, it presented an analysis based on many no-longer-existing uses and on historic water-quality data that reflected them. (In fact, one of the reasons EPA had limited uses as a result of reregistration was to address water quality concerns revealed by that data.) It also relied on a model that predicted the impacts of exposures of salmonids. The draft biop ultimately predicted that the registration of the three products would jeopardize the future of 27 of the 28 subpopulations (or ''evolutionarily significant units'' (ESUs)) of endangered or threatened salmonids.

The draft was subject to scathing criticism from EPA. The agency challenged, among other things, NMFS's failure to recognize the new restrictions that had resulted from reregistration, the Service's reliance on the older water monitoring data and several aspects of the modeling of potential impacts from pesticide use that NMFS employed.

In addition, as is routine for EPA (but unusual for many other agencies that consult with the Services), EPA opened a public docket to accept comments. Even more scathing comments were submitted by government agencies in the affected states, farmers and other growers who use the three products, and the products' principal registrants—the three companies that ultimately became the appellants in *DAS v. NMFS*.

Curiously, in preparing the draft biop, NMFS had not fully complied with the ESA and its own regulations by failing to previously seek input from either EPA or the pesticide registrants—who, in ESA terms, are the ''applicants'' for the action being evaluated.[17] At a meeting held later in August, 2008, NMFS staff asserted they had not done so because they could not identify the applicants—an assertion astonishing to the registrants, since the companies spend millions of dollars annually promoting their products and are by no means secretive about who markets them.

In any event, EPA, the states and the registrants backed their comments with extensive documentation. They also brought to several meetings the scientists who had authored studies that the registrants believed contradicted key elements of the Service's analysis. But NMFS gave all the comments and input short shrift. In November, 2008, it published a final biop that ignored almost all of the scientific criticisms and retained all but one of NMFS's ''jeopardy'' conclusions.[18]

The final biop also included (as required by the ESA and NMFS's regulations) sets of ''reasonable and prudent alternatives'' (RPAs) and ''reasonable and prudent measures'' (RPMs) that, if implemented by EPA, NMFS believed would adequately protect the salmonids.[19] Among other things, these included pesticide use ''buffers'' that precluded ground application of the subject pesticides within 500 feet of waters in any way connected to salmonid-bearing rivers—including drainage ditches and intermittent streams—or application from aircraft within 1,000 feet. Because agriculture relies on water, and fields and orchards are adjacent to rivers and irrigation canals, imposing such restrictions would be tantamount to banning the use of the three products on most farms and orchards in the four affected states.

III. The DAS v. NMFS Suit

The three registrants filed suit against NMFS in early 2009, asserting that the biop and its RPAs violated both the ESA's requirement that decisions be based on the best available science and, because NMFS had failed even to respond in it to the major scientific criticisms that had been made, the APA. After a two-year delay arising from the district court's initial conclusion that it lacked jurisdiction to hear the case,[20] Judge Alexander Williams of the U.S. District Court for the District of Maryland granted summary judgment to NMFS.[21] In doing so, Judge Williams expressed considerable skepticism about the biop's response to the criticisms aimed at it, but deferred to the Service's purported expertise and supplemental factual representations by the Service's staff and legal counsel.

In *DAS v. NMFS,* the Fourth Circuit reversed Judge Williams. A unanimous panel concluded that the biop ''was not the product of reasoned decision-making''[22] and failed to meet the fundamental requirements of the APA—to explain the Service's choices and respond to substantive comments.

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[16] ''The 1988 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorized EPA to conduct the pesticide reregistration program – a comprehensive review of the human health and ecological effects of pesticides first registered before November 1, 1984, to ensure that they met current scientific and regulatory standards. Through the reregistration program, EPA called in and reviewed supporting scientific studies, completed human health and ecological risk assessments, and developed risk mitigation measures as needed using current science, transparency, and input from stakeholders and the public. The results of EPA's reviews were summarized in Reregistration Eligibility Decisions (REDs).'' *Pesticide Reregistration Facts*, EPA, http://www.epa.gov/pesticides/reregistration/reregistration_facts.htm (last updated May 9, 2012).

[17] 16 U.S.C. § 1536(a)(3).

[18] Biological Opinion: Environmental Protection Agency Registration of Pesticides Containing Chlorpyrifos, Diazinon, and Malathion, Nat'l Marine Fisheries Serv. Endangered Species Act Section 7 Consultation (Nov. 18, 2008), available at http://www.nmfs.noaa.gov/pr/pdfs/pesticide_biop.pdf.

[19] *See* 16 U.S.C. § 1536(b)(3)(A) and (B); 50 C.F.R. § 402.02.

[20] *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 638 F. Supp. 2d 508 (D. Md. 2009), *rev'd*, 637 F.3d 259, 72 ERC 1353 (4th Cir. 2011).

[21] *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 821 F. Supp. 2d 792 (D. Md. 2011), *rev'd*, No. 11-2337, 2013 BL 45001 (4th Cir. Feb. 21, 2013).

[22] *DAS v. NMFS*, No. 11-2337, 2013 BL 45001 (4th Cir. Feb. 21, 2013), at *2.

First, however, the Court held that Judge Williams had impermissibly relied on justifications for NFMS's decision that were not presented in the biop. Instead, he had found many justifications in a supplemental affidavit from NMFS staff and arguments made by legal counsel for NMFS in their briefs. Citing a considerable body of case law, and rejecting NMFS's efforts to distinguish it, the Fourth Circuit held that this reliance was in error: a reviewing court may look only to contemporaneous justifications for agency action, not *post-hoc* rationalizations that did not actually inform the agency's decision making.[23]

The Fourth Circuit then turned to review of the biop itself. It found the biop unlawfully ''arbitrary and capricious'' for three specific reasons. First, the Court ruled arbitrary and capricious a key assumption in the model that supported NMFS's conclusions that salmonid populations were threatened by use of the three pesticides: that all salmonids would be continuously exposed to a lethal concentration of the pesticides over a 4-day period. Despite withering criticism from EPA and others on the draft biop that the assumption bore no relationship to actual exposure conditions in salmonid-bearing waters, NMFS had retained it in the final biop. The Service defended the assumption on the bases that acute laboratory tests often use a 4-day exposure period, that lethal pesticide concentrations can persist for more than four days, that young salmonids use shallow waters at some point in their life cycles, and that salmonids could be exposed more than once. But none of these justifications, the Fourth Circuit held, provide a satisfactory basis for explaining ''the rationality of [the assumption's] relationship to real-world conditions.''[24]

Second, the Fourth Circuit ruled that NMFS's reliance on outdated water quality data, and its lack of explanation for that reliance, was arbitrary and capricious. As noted above, several commenters had criticized NMFS's use of older water quality data when new data that more accurately reflected ongoing, actual pesticide use conditions were available. The Court stated that ''[w]hen an agency acknowledges that its data are either outdated or inaccurate, it should, at the very least, analyze the new data or explain why it nevertheless chose to rely on the older data.''[25]

Next, the Fourth Circuit held arbitrary and capricious the biop's recommended uniform ''buffer zones.'' As explained above, the ''reasonable and prudent actions'' set forth in the biop included prohibitions of ground and aerial applications of the pesticides within, respectively, 500 and 1000 feet of waterways. But the buffers were to be imposed regardless of channel depth or width, water flow rates, or a number of other factors which could significantly influence where and when salmonids could be exposed to pesticides. The Fourth Circuit held that although the biop addressed the need for large buffers in some habitat, it failed to explain why such buffers were appropriate elsewhere.

The Court also rejected NMFS's effort to escape the requirement of its own regulations, which require that recommended actions be ''economically and technologically feasible.''[26] NMFS's failure, the Court stated, ''effectively reads out'' the requirement in the ESA to take the economic impact of the buffers into consideration and made it impossible for the Court ''to review whether the recommendation . . . was the product of reasoned decision-making.''[27]

Finally, noting that it had addressed in its opinion only some of the alleged failures of NMFS's analysis, the Fourth Circuit not only reversed the judgment of the district court, but also vacated the biop and instructed the district court to send it back to NMFS so all of the issues could be ''aired and addressed in the renewed agency process.''[28]

IV. Putting DAS v. NMFS into Context

Understanding the significance of the *DAS v. NMFS* decision requires review of several other developments and principles.

First, the case that generated the chlorpyrifos-diazinon-malathion biop, *Washington Toxics,* was not unique. A number of similar cases resulted in EPA agreeing to consent orders setting schedules for consultations about the impact of a long list of pesticides on a number of other species.[29] This is in addition to pending cases in which the plaintiffs seek to compel consultations on the impacts of 381 pesticides on 214 species[30] and with regard to the impacts of over 100 registrations of two neonicotinoid pesticides on at least 18 species.[31]

EPA clearly hopes it will be able to head off the inefficient ''regulation by litigation'' produced by these suits by addressing all ESA consultation obligations in the context of the ''registration review'' process that has replaced the ''reregistration'' process described above. That registration review program, which was mandated by Congress in 1996 amendments to FIFRA, aims to review each pesticide's registration every 15 years to assure that the pesticide still meets the FIFRA standards for registration.[32] With last month's publication of its Stakeholder Policy, EPA has confirmed prior informal indications that it hopes to be able to use the registration review program to limit the number of cases in which consultation is necessary and to accelerate consultations where they must occur.[33] But it is by no

[23] *Id.* at *5-6; *see,e.g., SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943); *Citizens to Pres.Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971); *Motor Vehicle Mfrs. Ass'n v. State Farm Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

[24] *DAS v. NMFS*, 2013 BL 45001, at *10.

[25] *Id.* at *12.

[26] *Id.* at *13; *see also* 50 C.F.R. § 402.02.

[27] *DAS v. NMFS*, 2013 BL 45001, at *14.

[28] *Id.*

[29] *See Endangered Species Litigation*, EPA, http://www.epa.gov/espp/litstatus/eslitig.htm (last visited March 7, 2013).

[30] *See* Complaint, *Ctr. for Biological Diversity v. EPA*, No. 11-CV-0293-JCS (N.D. Cal. Jan. 20, 2011), ECF No. 1. For obvious reasons, this suit is often referred to as the ''Mega Case.'' *See also* 14 DEN A-13, 1/21/11.

[31] *See* Complaint, *Ellis v. Bradbury*, No. C-13-1266-LB (N.D. Cal. March 21, 2013), ECF No. 1. *See also* 56 DEN A-13, 3/22/13.

[32] 21 U.S.C. 346a; *See* 2011 Oversight Hearing at 37 (''EPA intends to meet its ESA obligations for pesticide registrations via the Registration Review Program.'').

[33] The policy outlines a strategy in which EPA essentially would convince registrants and growers to redefine product uses in ways that would allow the Agency to conclude that continued approval of registrations would have no effect on threatened or endangered species or their habitat, which would eliminate EPA's consultation obligation, or would make it possible for the Agency to more quickly convince the Services that full-scale, ''formal'' consultations are not necessary.

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means certain that the agency will prevail with this strategy.

Second, evaluating the impact of pesticides on threatened and endangered species is very complex. For one thing, not only are there now over 600 listed animal species, over 800 listed plant species, and more on the way—there is no good data base that maps where these species are found. In part, this reflects resistance from species-protection advocates to providing a roadmap for those who might wish to extinguish species. But it also reflects the difficulty of mapping locations with adequate granularity and matching maps of species locations with those of pesticide usage areas.

Similarly, many of the concerns associated with the potential impacts of pesticide use on threatened and endangered species raise complex scientific issues. In the context of the salmonid species of concern in *DAS v. NMFS*, for example, analysis needed to bring together biological information on the life history of salmonid populations—where the fish are found, when, and at what life stage—with predictions of how much pesticide would exist at relevant waterways as a result of authorized uses and evaluation of the toxicological impacts of the resulting exposures. The disciplines for developing and using key inputs to these analyses are at varying stages of maturity. The same is also true as to similar questions pertinent to potential pesticide impacts on many other species, aquatic and nonaquatic, animal or plant. Indeed, this is a major reason for the NAS effort mentioned earlier in this article.

Third, the Services do not have the staff to do the amount of work necessary to address all these questions, even for a reduced number of consultations. For example, at May 2011 oversight hearings before the House Natural Resources and Agriculture committees, NMFS was asked how much more staff it would need to be able to keep up with requests for consultation from EPA. NFMS estimated that it needed approximately 40 additional full-time employees and $6 million per year to support them.[34] That estimate seems to many observers low. At best, however, it was based on ''business as usual'' in consultation, not on the greater level of documentation that *DAS v. NMFS* now requires. It also reflected only NMFS's needs, not the needs of its sister agency FWS. FWS faces even greater burdens than NMFS, in light of its responsibilities for the many threatened and endangered species outside of NMFS's jurisdiction. Nor have the pesticide biops undertaken in recent years involved nationwide assessments of a pesticide on multiple species. All that one can be sure of today is that many, many more Services staff would be required to avoid having the need for EPA to consult slow the registration program considerably, perhaps to a halt.

Fourth, however, FIFRA imposes on EPA very clear obligations to move registration actions ''as expeditiously as possible''[35] and in accordance with statutorily specified deadlines. Congress in 2004 enacted the Pesticide Registration Improvement Act (PRIA) and has reauthorized it twice since.[36] In doing so, Congress set specific deadlines for a long list of registration actions. The chairman of the Senate committee in which the bill originated explained to his colleagues that the deadlines were needed because a ''slowdown in consideration of [pesticide] applications is neither in the interest of the environment, nor of the farmers or chemical manufacturers . . . . [PRIA] ensures that [pesticides] are reevaluated in a timely manner.''[37] But there is no way these deadlines can be met if consultations are sought in even a portion of the applications for registration or amendments that EPA considers.

Finally, a process put in place in 2004 to try to facilitate EPA and the Services' integration of FIFRA and ESA responsibilities has not worked. In 2004, under considerable pressure from the Bush White House, the Services promulgated a set of FIFRA-specific ''Counterpart Regulations.''[38] Under the process they established, EPA was to have authority to make the threshold judgment of whether the registration action at issue was or was not ''likely to adversely affect'' a species of concern (a decision that otherwise rests with the Services). If EPA concluded it was not, there would be no further need for consultation. In addition, if consultation were necessary, EPA could prepare both the preliminary environmental assessment that defines the scope of a biop, and the biop itself, subject to Service review of each document. But the regulations imposed tight deadlines for those Service reviews.

Environmentalists challenged those regulations, and in 2006, the same district court that had decided *Washington Toxics* ruled unlawful allowing EPA to make ''not likely to adversely affect'' decisions.[39] At the same time, the court left the remainder of the regulations intact. But they have proved unworkable. When EPA has sought to invoke its remaining Counterpart Regulation authority, the Services have created roadblocks. For its part, NMFS simply ignored EPA's submissions; FWS told EPA that the agency's submissions were incomplete, and refused to proceed.[40] EPA briefly protested, but then let the matter drop.

EPA's new Stakeholder Policy is a laudable effort to try to revive cooperation between the agency and the Services, and was ''developed jointly''[41] with the Services (although issued only by EPA). But the only clear commitment by the Services that it embodies is to convene a meeting with registrants where EPA requests consultation to determine what ''additional information'' the registrants may have that could assist the Service. Participation by others in these meetings is to occur only because EPA (not a Service) will invite the U.S. Department of Agriculture to attend and, ''[i]f the Services believe that changes to the pesticide label may be necessary to avoid or reduce the extent to adverse effects to listed species or critical habitat, they will work with EPA and USDA to engage the applicant, product

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[34] 2011 Oversight Hearing at 44.

[35] 7 U.S.C. § 136a(c)(3)(A).

[36] Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, 118 Stat. 3; Pesticide Registration Improvement Renewal Act, Pub. L. No. 110-94, 121 Stat. 1000 (2007); Pesticide Registration Improvement Extension Act of 2012, Pub. L. No. 112-177, 126 Stat. 1327.

[37] 149 Cong. Rec. S14,496 (daily ed. Nov. 12, 2003) (statement by Sen. Harkin).

[38] 50 C.F.R. §§ 402.40-48; 69 Fed. Reg. 47,732 (Aug. 5, 2004). *See also* 147 DEN A-2, 8/2/04.

[39] *Wash. Toxics Coal. v. Dep't of Interior*, 457 F. Supp. 2d 1158 (W.D. Wash. 2006).

[40] Letter from Marjorie A. Nelson, Chief, Fish and Wildlife Serv., to Arthur-Jean B. Williams, Assoc. Dir., Envtl. Fate and Effects Div., EPA (Jan. 14, 2009), available at http://www.epa.gov/espp/litstatus/consultation_rejection_fws.pdf.

[41] Stakeholder Policy at 1.

users and other stakeholders to discuss possible label changes . . . .''[42] Past experience suggests that if this is the strongest commitment to outreach that EPA was able to obtain from the Services, one cannot be optimistic that EPA's strategy will repair many of the existing problems.

V. What Are the Implications of the New Decision?

Most fundamentally, the *DAS v. NMFS* decision means even more work for Services already incapable of keeping up with consultation requests from EPA. Over the next decade–and even if the new Stakeholder Policy is successful—such requests probably will be forthcoming at a pace of dozens a year, generated both by lawsuits, the statutorily mandated registration review program, and perhaps requests pertaining to new chemical registrations.

Some data on these burdens are available. In response to congressional questions posed after the 2011 oversight hearing, EPA told Congress that between July 2002 and May 2011, the agency had submitted 147 consultation requests to either the FWS or NMFS, either under court order or consistent with a schedule in a settlement agreement or stipulated injunction. NMFS had issued biological opinions in response to 21 of these, and FWS had delayed action on several dozen of these on the grounds that EPA had not provided enough information. EPA had received no response whatsoever as to 77 requests. Rowan Gould, the acting director of FWS, candidly told the committees that, ''[f]rom the Fish and Wildlife Service's perspective, [FIFRA-ESA] suits have been particularly problematic because sometimes they are on process. There are very specific time lines under the ESA for our listing process and other responsibilities. And we are seeing some of these petitions of well over 200-300 species coming in at a time. We literally are swamped.''[43]

In fact, 56 months after agreeing to complete biological opinions on 37 pesticides, NMFS has completed only a subset of biops arising from *Washington Toxics*. Much more effort will be required for each multispecies, national evaluation. Those biops thus will be far more complex than the biop considered in *DAS v. NMFS*.

But litigation and registration review are not the sole generators of foreseeable consultation requests. EPA also annually takes thousands of other registration actions. These range from approving minor changes in label language, to authorizing new uses in new areas, to approving entirely new pesticides. Some of these also may trigger additional consultation requirements.

In each of these contexts, registrants can be expected to challenge any views or conclusions asserted by the Services that the registrants believe inconsistent with good science. Moreover, the registrants—who by definition focus principally on the science issues associated with their proprietary products, not on broader issues faced by the Services—can be expected to have far more familiarity with the questions pertaining to their products than the Services' staffs. While the Services will be no more bound to accept the arguments and references presented by registrants than they were before *DAS v. NMFS*, after that decision they will have to be far more comprehensive in addressing concerns raised by registrants and, where the Services' scientists disagree, explaining the basis for their contrary conclusions. In practice, this translates to more effort and, absent a huge increase in Services' staff resources, more delay.[44]

Moreover, all of these FIFRA-oriented tasks come on top of the Services' obligations to consult on other federal actions. In recent years, for example, NMFS has produced a yearly average of 36 biops on projects having nothing to do with pesticides.

Overall, this situation is a recipe for tying the FIFRA registration review process in knots, blocking valuable new products from reaching farmers, overwhelming the Services and—perhaps most important for those more concerned with species protection than pesticide matters—frustrating the ultimate goal of evaluating impacts on and ultimately protecting endangered and threatened species. No interest group—farmers, pesticide manufacturers, government officials, or those simply interested in assuring effective, efficient regulatory programs—can find this outcome acceptable.

VI. Solutions

One solution to the train wreck described above would be to substantially increase the staffs and funding of the Services, focusing particularly on the areas of expertise pertinent to evaluating ecological effects of pesticides. But it is fantasy to believe this is possible given current political realities. So the answer must be found elsewhere.

In the short term, it may be found at EPA. That agency appears to have several available tools for sidestepping consultation and its inevitable delays. And these tools are not mutually exclusive.

One would be for EPA to organize the data pertinent to ESA-mandated decisions in a way that would substantially simplify analyses. For example, data bases showing where various crops are grown and pesticides used could be integrated with information on species habitat. EPA reportedly is working on such an effort, but available information on specific species locations is remarkably limited, and the data management challenges the agency is addressing are complex.

Second, using this data system or information EPA obtains from applicants may allow EPA to conclude that continued authorization of existing uses would have no effect on threatened or endangered species. That finding would obviate the need for consultation. The Stakeholder Policy confirms that EPA is testing this approach

[42] Id. at 9.

[43] 2011 Oversight Hearing at 93.

[44] The Stakeholder Policy is not encouraging about this concern. Although EPA apparently was able to obtain from the Services a statement that they intended to respond to comments, it is carefully hedged: ''Upon receipt of the *organized* public comments from EPA, each Service will prepare a document for their respective options, *where applicable*, and include it in the administrative record that addresses how comments were considered and, if appropriate, how the final document was modified to address the comments . . . . Both the Services and EPA will make the document available to the public *upon request*.'' Stakeholder Policy at 10 (italics added). This is hardly a commitment to the meaningful analysis and explanation that *DAS v. NMFS* mandates.

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now in the registration review program but, again, existing data constraints are very real.

A third approach, also confirmed by the Stakeholder Policy, would be for EPA to sufficiently involve the Services in its evaluations that ''informal'' consultation procedures obviate the need for formal consultation. But experience, and absence of any commitment whatsoever from the Services to cooperate in informal consultation (hedged or otherwise) suggests that this is a chimera.

An additional administrative solution would be for EPA to invoke authority granted to the agency in the Services' 2004 Counterpart Regulations. One of the portions of those regulations that survived judicial challenge appears at 40 C.F.R. § 402.46. It authorizes EPA to prepare a biological opinion, including RPAs and RPMs, and to submit it to the appropriate Service for review. The Service then has 90 days to either accept EPA's conclusions or provide an alternative draft biop. Given the demands on the Services' resources, it seems highly unlikely that this Service authority would be exercised, however, absent gross error on EPA's part.

Could EPA complete the necessary biops any more quickly than the Services? There is good reason to believe the answer is yes. The agency already undertakes ecological risk assessments, and has a large staff in place that possesses the appropriate expertise. Unlike the Services, its staff is focused on pesticide-related issues. In addition, EPA's record of putting in place administrative data bases and systems that allow timely completion of complicated scientific reviews is good—far better than that of either of the Services. This was demonstrated by EPA's successful modification of its registration program to meet the extensive new demands imposed by the 1996 Food Quality Protection Act.[45] And, unlike the Services, EPA routinely prepares responses to comments on proposals it makes available to stakeholders. So EPA should not find compliance with *DAS v. NMFS* and the APA to be a particular challenge.

However, EPA to date has been reluctant to invoke even its lesser Counterpart Regulation-granted authority to prepare biological assessments—the first step in developing a biological opinion—and obtain prompt Services' concurrence or critiques of them. As noted above, the agency tried to invoke this authority, only to meet a bureaucratic rejection from NMFS in 2009.[46] NMFS's objections were not well founded, but EPA has taken no intragovernmental action to follow up and enforce its rights. And the recently released Stakeholder Policy's discussion of formal consultation does not refer to proceedings under the Counterpart Regulations.

Perhaps publication of the forthcoming NAS report will stiffen EPA's spine in these matters. If so, the existing Counterpart Regulations could provide at least an initial mechanism for overcoming some of the frustrations described above.

In the absence of new funding, data development and management breakthroughs, far better interagency cooperation, and use of a Counterpart Regulation-based solution, the only alternative appears to be statutory relief. This may not be as far-fetched as might initially be assumed because the FIFRA-ESA situation uniquely involves seeking the Services' advice for another agency that already has considerable environmental-protection and enforcement credentials. And the FIFRA-ESA issues could be addressed without undertaking any other changes to the ESA.

What form might legislation take? There are several options. Congress could simply exempt FIFRA pesticide decisions from the scope of the ESA mandate. This would not mean that endangered and threatened species would go unprotected because FIFRA's requirement that no registration be approved if it presented an ''unreasonable adverse effect on the environment'' would still remain operative.

Other alternatives could totally shift from the Services to EPA responsibility to evaluate the implications of pesticide registration actions on threatened and endangered species, or to incorporate in statute elements of the original Counterpart Regulations. The latter approach would grant EPA authority to make the determination that proposed pesticide uses are ''not likely to adversely affect'' any threatened or endangered species, but would also have to authorize EPA to issue ''incidental take statements'' to be comprehensive.[47] These approaches could be accomplished with simple amendments to the ESA, which could be limited to circumstances in which EPA was exercising its FIFRA responsibilities, without opening up other issues or affecting that statute's application to other federal agency actions.

There no doubt are other approaches that also could ameliorate the current and foreseeable regulatory paralysis. Whichever are chosen, however—and they are not mutually exclusive—the *DAS v. NMFS* decision underlines the need for some corrective action promptly to be undertaken.

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The opinions in this article do not represent the views of Bloomberg BNA, which welcomes other points of view.

[45] Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489 (1996).

[46] *See infra* footnote 40; *see also* Letter from Patricia K. Hirsch, Acting Gen. Counsel, EPA, to Arthur E. Gary, Acting Solicitor, U.S. Dept. of the Interior (July 2, 2009).

[47] Inclusion in a biop of an ''incidental take statement'' protects EPA and others from ''takings'' claims under Section 9 of the ESA. *See* ESA § 7(b)(4)(C), 16 U.S.C. § 1536(b)(4)(C).