

EPN Oral Comments on EPA and FDA's Proposal to Modernize the Approach to the EPA and FDA Oversight of Certain Products

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My name is Bill Jordan. I am a member of the <u>Environmental Protection Network</u> (EPN). EPN is an NGO that harnesses the expertise of more than 550 former EPA career staff and confirmation-level appointees to provide the unique perspective of former regulators and scientists on matters involving or affecting the EPA. I have five points:

- 1] There are many product categories that could be called either pesticides or new animal drugs. In addition to pet collars and spot-ons and genetically engineered insects, they include: livestock dips, bird repellents, deer and rat contraceptives, and products to treat fish in aquariums and aquaculture, to name a few. EPA and FDA need to think of a principled way to decide which agency regulates which categories.
- 2] EPA and FDA should draw the jurisdictional line between the agencies based on which agency would do a better job of regulation. That means looking not just at an agency's expertise and resources, but also at the scope of its legal authority. We think the agencies should consider the types of risks that different product categories could pose. FIFRA gives EPA broad authority to regulate all kinds of pesticide risks. EPN, however, questions whether FDA has the legal authority to regulate a new animal drug based on its risks to the environment.
- 3] If EPA and FDA agree to change the jurisdictional line, they need to think about how to manage the transition for products that move to a new regulator. The White Paper did not address this. If a product category moves from FIFRA to FDA, it will be easy for EPA, but FDA will have to figure out what to do about products previously deemed pesticides that are labeled and in channels of trade or in the hands of users. The opposite would be true if products move from FDA to EPA.
- 4] EPA and FDA should provide a portal where the regulated community can get timely answers to the question: who regulates my product? Companies are often confused, and agency guidance can be unclear or non-existent. Both agencies should have a formal forum to answer questions.
- 5] EPA and FDA could change or simply clarify jurisdictional lines through administrative tools. FDA and EPA have addressed these sorts of issues in the past and have conveyed their position using MOUs, public guidance, and/or rule-making. These approaches are quicker and allow for more nuance and flexibility. These approaches have worked; the agencies do not need new legislation.