CropLife ☆AMERICA☆

March 31, 2009

Kevin F. Neyland, Acting Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th St NW
Washington, DC 20503

Dear Mr. Neyland:

CropLife America is the national trade association representing the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers. We take this opportunity to comment on the federal regulatory review process, according to the invitation published in the Federal Register on February 26, 2009 (74 FR 8819). The comment period allowed is impossibly short for industries and other stakeholders to conduct the analyses and find the case studies that would best inform this process. Likewise, the 100-day response time directed by the President for federal agencies is inadequate for shaping a process that influences hundreds of billions of dollars in costs and benefits to society. We believe that an open forum or forums with broad participation would be important to properly inform decision makers who will be formulating any revision to the federal regulatory review process. Lack of comment or abbreviated comments on specific issues raised in the FR notice indicates lack of sufficient time to respond, rather than lack of interest on the part of CropLife America.

The crop protection industry is one of the most highly regulated industries in the USA. We depend on competent federal agencies to assure that the rules are fair and strictly enforced. Without a strong and fair regulatory system, health of the general public, safety of agricultural workers, and the environment could easily be jeopardized by inadequately tested products, or vague and inappropriate use directions for pesticide products. The incentives to develop innovative technologies for crop protection would be seriously compromised. Individual crop protection companies and the industry as a whole take very seriously and conscientiously their stewardship role with respect to public welfare.

We appreciate this step to seek public input on the federal regulatory review process. Limiting the opportunity for input to federal departments and agencies could have produced a biased and skewed picture of the need for regulatory review. Individual agencies have a high level of expertise in their respective areas of responsibility and are highly focused on somewhat narrow goals. There can be strong motivation on the part of some agency personnel to circumvent requirements of regulatory review and avoid the burdens placed on them by OMB. The public and the various regulated entities have strong interests in the regulatory review process from multiple perspectives to ensure that (1) regulatory burdens are fair and fairly distributed among regulated entities; (2) regulation achieves statutory and policy goals in the most efficient and

least onerous manner; and (3) regulation fosters and encourages, rather than stifles innovation that is essential to solve societal problems and meet societal needs. These interests are protected in no small measure by the role of OMB.

General Principles:

EO12866 as originally issued has functioned quite well in assuring oversight of federal regulations. Preservation of a strong role for OMB/OIRA in review of individual proposed and draft final regulations promulgated by federal departments and agencies is vital to ensuring that regulations are coordinated among agencies, serve the needs of American business and the American public in the lease onerous and most efficient way, comply with all directives in applicable legislation, are least likely to be challenged in litigation, etc. Each and every regulation is promulgated by a federal executive department or agency dependent on authorization from one or more laws enacted by the Congress. OIRA's function to review individual regulations is essential in carrying out the President's Constitutional responsibility to "… take Care that the Laws be faithfully executed …" (U.S. Constitution, Article II, Section 3).

In Executive Order 13497, President Obama directs OMB and federal agencies to "promptly rescind any orders, rules, regulations, guidelines, or policies implementing or enforcing" the Bush Administration revisions to EO12866. We request that OMB –

- explain how "promptly" is interpreted in this regard;
- release publicly and without delay a listing of what it has rescinded in compliance with this provision, and what is yet under active consideration to be rescinded;
- explain the status of any orders, rules, regulations, guidelines, and policies pertinent to the Bush Administration revisions that may still have relevance and thus would not be fully rescinded;
- track agency actions taken to comply with this provision and require them to report to OMB;
- report without delay to the public in a centralized location or web site all orders, rules, regulations, guidelines, and policies that individual agencies have rescinded in compliance with this provision; and
- explain if and how rules and regulations can be "rescinded" without notice-and-comment rulemaking.

OIRA review of individual federal regulations is an essential step in the overall scheme of checks and balances that assures good government. Individual federal agencies, of necessity, have a more narrow focus in their respective areas of responsibility. OIRA provides the eyes and ears for the President to evaluate the broad picture, to determine if regulations meet and contribute to overall national goals without placing unwarranted burdens on any one segment of society. Lacking this oversight, the President's ability to judge the value of regulations and how well they protect health, environment, or economic well-being, or provide for the common welfare is seriously diminished.

Guidance Documents

We believe that it is essential to include guidance documents in the federal regulatory review process. Professor Adrian Vermeule, Harvard Law School, articulates an important rationale for doing so:

> One of the major differences between the regulatory review orders of Presidents Reagan and George W. Bush, on the one hand, and President Clinton, on the other, was that the former covered guidance documents and interpretive rules while the latter covered only regulations intended to have the force and effect of law. I believe the former approach is correct and deserves bipartisan approval. Covering only legislative regulations distorts agencies' incentives, causing some marginal substitution of guidance documents for legislative rules merely to avoid OMB oversight. There is no social benefit to that effect. (3/5/2009 letter to Jessica Hertz, OMB; http://www.reginfo.gov/public/jsp/EO/fedRegReview/adrian_vermeule.pdf)

Promulgating regulations has become an arduous, painful, and resource-intensive process for federal agencies. Much of that pain, including review by OIRA, is necessary to make sure that government "gets it right" the first time. But because of it, notice-and-comment rulemaking may be considered as a "last resort" for meeting a particular regulatory need, thus pushing such actions into the realm of guidance more often than the "marginal substitution" mentioned by Professor Vermeule.

Furthermore, guidance documents can have an economic impact on industry and the public that is on a par with regulations. Guidance documents and guidelines promulgated by federal agencies may carry disclaimers stating or implying the (semi-)voluntary nature of the guidance, such as, "… this notice is not binding on either [the agency] or [regulated entities], and [the agency] may depart from this guidance in individual circumstances. Likewise, [regulated entities] may assert that the guidance is not appropriate for a specific [action]." Nevertheless, an agency can carry a big stick: it can delay or deny, either explicitly or implicitly, necessary business permits or approvals, or exact penalties, based on a regulated entity's challenge to guidance provisions that may not be appropriate for a given circumstance. This can result in unfair market disruption, unlevel playing field, or denial of business opportunities for regulated businesses, as well as withholding of beneficial products and services from the public. Hence, impartial review of guidance documents by OIRA, equivalent with regulations, is indeed warranted, and its importance is underscored.

Peter Orszag's memo (M-09-13) of March 4, 2009 (http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m09-13.pdf) regarding "Guidance for Regulatory Review" confuses rather than clarifies the situation. EO13497 on January 30, 2009 repealed EO13422, explicitly deleting all mention of guidance documents from EO12866. Mr. Orszag's memo of a few weeks later says that EO13497 has "restored the regulatory review process to what it had been … between 1993 and 2007", when guidance documents were not covered under EO12866, while assuring that "significant policy and guidance documents … remain subject to OIRA's review under EO12866." OMB must consider that these apparently conflicting documents might leave the regulated community confused as to the current state of federal guidance documents.

Independent Agencies

We believe that certain independent agencies should be brought under the federal regulatory review process. CropLife America has not had adequate time or opportunity to develop the comments and rationale on this subject.

Specific Issues:

- **The relationship between OIRA and the agencies**

We believe that OIRA should continue and enhance its role in review of individual regulations. We concur wholeheartedly with the Presidential Memorandum of January 30, 2009 that "... if properly conducted, centralized review [of federal regulations] is both legitimate and appropriate as a means of promoting regulatory goals."

Professor Shane of Ohio State University instead recommends that OIRA be limited to a "coordination function", to –

> ... lead a series of government-wide efforts to examine on a systematic basis an entire range of federal regulations, across agency boundaries, that are relevant to some particular set of social goals in order to determine whether existing regulations fit together as a whole, whether their distributional impacts are fair, and whether portions need updating (or, indeed, repeal).
> (http://www.reginfo.gov/public/jsp/EO/fedRegReview/Peter_Shane.pdf)

Professor Shane then correctly notes that "No single-mission agency can perform this job." However, we would counter that the nation, regulated industries, and individual regulated entities cannot afford to wait until costly, frustrating, and perhaps dangerous mistakes are made with one or multiple individual regulations in order to evaluate whether they "fit together as a whole" or "whether portions need updating". No single-mission agency has or can have the fool-proof system of internal checks and balances in place to assure that those conditions are met for individual regulations, either. OIRA must make those evaluations and judgments for individual regulations on a continual basis, as they are proposed and promulgated, not waiting until years or decades later.

In 2008, the Federal Register's 80,700 pages published more than 5,000 separate final regulatory actions authorized under the various different federal statues, from the multitutde of different offices in all federal departments and agencies (including the independent agencies). There is no indication that 2009 will see a decrease in the number of final regulatory actions. That level of complexity inevitably results in a great many potential conflicts among regulations from different agencies and departments affecting the same regulated entities for different, but sometimes closely parallel purposes. The "policeman" role played by OIRA in reviewing the individual regulations as required, uncovering the potential conflicts, and resolving those conflicts, is essential to the economic viability and even the survival of the regulated entities.

- **Disclosure and transparency**

EO12866 has largely satisfied the need for disclosure and transparency in the regulatory review process through posting of notices of meetings with stakeholders and written material submitted by interested parties on specific regulatory review actions. It is important for all to understand who all, both within government and from among non-government stakeholders, has a voice or

expresses a view that is considered by the agencies in crafting regulations and by OIRA in reviewing the regulations. There should be no "back door" or "under the table" routes for influencing the content of regulations and the regulatory process, whether by regulated entities, government officials at any stage or level of the process, or other stakeholders.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) has a useful model for contributing to transparency in the regulatory review process, which is deserving of further discussion and expansion to other statutes, regulations, and agencies. FIFRA §25(a)(2) requires that each draft or final regulation prepared by the Administrator of the Environmental Protection Agency under the Act be provided to the Secretary of Agriculture and to the Congressional committees of jurisdiction over FIFRA prior to publication, with public notice in the Federal Register at the time the regulation is forwarded to the Secretary. The Secretary's comments and the Administrator's response must be published together with the proposed or final regulation.

The procedures for disclosure and transparency should be carefully considered. They should not be so rigid and burdensome as to discourage interaction among relevant government agencies, OIRA, and interested stakeholders; or to inhibit the necessary and productive candor between agencies and OIRA; or to prolong and delay the review process unnecessarily.

- **Encouraging public participation in agency regulatory processes**

OIRA review is essential to ensure that agencies have complied with statutory, regulatory, and guidance requirements for providing opportunities for public comment and input on the content of federal regulations. Allowing and achieving adequate public participation can be a labor-intensive and frustrating process, and agencies might often be tempted to overlook or short-change important steps. OIRA is in a unique position to observe which strategies for public participation work well for some agencies, and which fail to achieve desired results in other agencies. OIRA can establish guidance for agencies and recommend measures (through legislation or otherwise, as necessary) to specific agencies or to all agencies across the board for improving the level, quality, and efficiency of public participation.

Additionally, OIRA can increase the efficiency and utility of the regulations.gov web site for receiving public comment of federal regulations. OIRA should engage users of that web site on a broad scale to ferret out problems and solicit suggestions for improvement. While it is a vast improvement over submitting comments by paper, the web site can still be rather cumbersome and counterintuitive.

- **The role of cost-benefit analysis**

CropLife America strongly recommends that OIRA retain cost-benefit analysis in the review of federal regulations. In his comments, Eric Posner of the University of Chicago Law School succinctly summarized the rationale for doing so and presents several cogent recommendations, which are worth citing here for emphasis (see http://www.reginfo.gov/public/jsp/EO/fedRegReview/Eric_Posner.pdf):

> "Cost-benefit analysis has two virtues. First, it helps ensure that the executive branch devotes its [scarce] resources to correcting the worst problems at least cost. Second, it promotes transparency. A cost-benefit analysis reveals the assumptions of regulators, which enables the public, regulated parties, and courts to challenge and criticize

> regulations that are poorly designed. … Until a superior decision-procedure is developed, cost-benefit analysis should be retained.
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> "… Agencies sometimes simply refuse to estimate costs or benefits on the ground that the estimate is infeasible; at other times, they provide ranges. As a result, the cost-benefit analysis is impossible to evaluate. This loophole should be closed. Agencies should be required to estimate all of the relevant costs and benefits of the proposed regulation. They should also give confidence intervals where appropriate.
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> "… Agencies should permit interested parties to submit proposed regulations along with cost-benefit analyses, which should be reported to OIRA. The agency's proposed regulation should be approved by OIRA only if its cost-benefit ratio is superior to those of the alternative regulations.
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> "… Different regulations often have similar effects — for example, reducing the incidence of a particular disease or injury. Where they do, agencies should use the same valuations. This is not the current practice. To remedy this problem, OIRA should establish a central, publicly accessible database of valuations. OIRA should establish a valuations office that keeps track of valuations and solicits outside peer-reviewed studies to refine and update existing valuations and develop new ones. The list of standard valuations should include the discount factor, the benefit from an incremental reduction in the risk of death, the benefit from avoiding various injuries and illnesses, and so forth. When performing cost-benefit analyses, agencies would be required to use these OIRA-approved valuations. [Emphasis in original.]
>
> "… Agencies' cost-benefit analyses should be subject to peer review."

In its September 30, 1997 "Report to Congress on the Costs and Benefits of Federal Regulations", the Clinton Administration summarized (p. 10):

> In short, regulations (like other instruments of government policy) have enormous potential for both good and harm. Well-chosen and carefully crafted regulations can protect consumers from dangerous products and ensure they have information to make informed choices. Such regulations can limit pollution, increase worker safety, discourage unfair business practices, and contribute in many other ways to a safer, healthier, more productive, and more equitable society. Excessive or poorly designed regulations, by contrast, can cause confusion and delay, give rise to unreasonable compliance costs in the form of capital investments, labor and on-going paperwork, retard innovation, reduce productivity, and accidentally distort private incentives. The only way we know to distinguish between the regulations that do good and those that cause harm is through careful assessment and evaluation of their benefits and costs. Such analysis can also often be used to redesign harmful regulations so they produce more good than harm and redesign good regulations so they produce even more net benefits. (http://www.whitehouse.gov/omb/inforeg/chap1.aspx)

Many critics of the federal regulatory review process oppose cost-benefit analysis, sometimes citing analyses and figures purportedly demonstrating that the review process itself is overly burdensome. However, it is inherently difficult to compare the results we can see to "what might have been." A common limitation of cost-benefit analysis to date is lack of transparency on the alternatives for a given regulation that were considered and discarded as a result of judicious review by OIRA, and what they would have cost to society and regulated entities. Critics

produce estimates of the cost to society of delaying beneficial regulations, while ignoring the savings to society of avoiding bad regulations.

Now, during a review of potential revisions to EO12866, would be an ideal opportunity to undertake an open, systematic, and thorough cost-benefit analysis of the federal regulatory review process itself, as conducted by OIRA. Regulated entities and sectors could be invited to nominate case studies for consideration. Thoughtful analysis and testimony could be considered by whatever commission receives this assignment. The assignment could include rigorous cost-benefit analysis of representative active regulations to compare actual results with those predicted by the respective agencies in their analyses conducted for OIRA review, prior to promulgating the regulations. The resulting report and recommendations would be presented to the President for consideration in revising EO12866.

CropLife America recommends that any revision of EO12866 retain or reduce but not increase the $100-million economic-impact threshold for designating "major rules" that require OIRA review and cost-benefit analysis. Furthermore, OIRA should increase its scrutiny of agencies' conclusions that proposed rules do not meet this threshold, as there is typically no analysis presented to justify the conclusion. Small businesses can suffer inordinately the burdens of regulation which may not have a total societal impact of $100 million.

- **The role of distributional considerations, fairness, and concern for the interests of future generations**

Distributional considerations must take into account two fundamental concepts from industry's perspective. First, the burdens of regulation must be fairly distributed across competing businesses, from small to large, so that they do not create unfair competitive advantages or disadvantages for any one business or business segment. OIRA, in partnership with the Small Business Administration, operating under RFA and SBREFA, plays a pivotal role in assuring a level playing field for industry.

Second, onerous, excessively burdensome regulation stifles business innovation and development, robbing society as a whole of beneficial and improved products and services, as well as opportunities for employment and prosperity. If regulations impose undue burdens on industry, the costs of compliance deplete resources that could otherwise be used to expand business, invest in innovation, and drive economic development that powers our nation.

CropLife America has not had adequate time and opportunity to consider all the ramifications of distributional considerations, fairness, and concern for the interests of future generations.

- **Methods of ensuring that regulatory review does not produce undue delay**

CropLife America is sensitive to delays in promulgating regulations. Our industry has suffered from time to time when such delays have led to prolonged uncertainty for affected businesses. We offer the following suggestions for consideration.

  - Provide adequate resources and staff for OIRA to accomplish this essential task. Since its organization in the early 1980s, the staff of OIRA has shrunk by approximately 50%, while its mission and responsibilities have expanded significantly.

- Provide clear guidance to federal agencies on how they must conduct the analyses required by legislation and the review process in order to promulgate regulations. This would improve the quality of regulations overall and reduce delays and need for rework on agency materials after the OIRA review process has begun for a particular regulation.
- Involve OIRA earlier in the development of regulations by federal agencies, in order to ensure that the regulations going for final review by OIRA are indeed well crafted and ready for review.
- Existing OIRA guidance to federal agencies regarding preparation and promulgation of regulations and guidance should be re-proposed for public comment, in order to elicit ideas for improvement.
- Establish clear timelines for the regulatory review process, and hold federal agencies to those timelines.
- Resolve differences and conflicts with statutory and court-imposed deadlines on the promulgation of regulations that would circumvent or short-circuit the regulatory review process. Congress and the courts must carefully take into account the essential regulatory review process when establishing such deadlines for promulgating regulations. Agencies must build OIRA review into their timetables for development of regulations subject to statutory and court-imposed deadlines.
- Much of the potential for delay in regulatory development occurs well before OIRA becomes actively involved in review of individual regulations. Interagency review, whether formal or informal, though essential, can be time consuming. Full public disclosure of the comments and responses handled in interagency review, as recommended above in "Disclosure and Transparency", can reveal the extent to which the interagency review affects timing of development and submission for OIRA review.

This issue merits additional analysis and discussion.

- **The role of the behavioral sciences in formulating regulatory policy**

CropLife America has not had adequate time and opportunity to consider this issue.

- **The best tools for achieving public goals through the regulatory process**

CropLife America has not had adequate time and opportunity to consider these issues.

Additional Considerations

Any revision of EO12866 should explicitly require consideration of the impact of regulations, individually and in the context of the broader regulatory framework, on international trade and investment by U.S. businesses.

CropLife America looks forward to an ongoing public discussion and debate as revisions to EO12866 are considered.

Sincerely,

Ray S. McAllister, Ph.D.
Senior Director, Regulatory Policy