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Possible Controls over the Bending of Regulatory Science

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INTRODUCTION

BELLEROPHON TAMING PEGASUS', the monumental statue shadowing the formal entrance to Columbia Law School, states in metaphor the tension that motivates this piece. Nominally it reflects reason taming unreason, which is the role that law claims in society. One knowing a bit of its history sees more. Commissioned in the early 1960s, its earliest sketches reflected a proportion and a distance between man the master and the winged horse of unreason suggesting optimism that the outcome was secure. The golden bridle would do its work and reason would prevail. As the early 1960s became the late 1960s, Pegasus grew in the sketches, Bellerophon shrank, and ultimately the two merged. Now Pegasus was Bellerophon's own head; the bridle was around his own neck; the horse's expression of pain and rage was his own. And as Bellerophon could never completely tighten the noose around his own neck if he wished to live, one knew that the struggle could not be resolved. Reason and unreason continuously contend. What a metaphor for the project of law!

In particular, what a metaphor for the continuing tensions between objective ('scientific') and political inputs to regulatory decision-making. For science as for law, the ambition is for 'reason', for analysis as free as it can be of the influence of 'man'. Here's a strong statement of that position, that might be taken as scientists' equivalent of 'government of laws and not of men'.

Science is, and can only be, descriptive and explanatory. Whether a scientific finding is judged to be accurate is dependent on the quality and rigor of the methods used and

* Betts Professor of Law, Columbia Law School, Columbia University, New York, NY. This chapter, first shown in draft to the conference on global administrative law in whose volume it appears, has gained much from colleagues at the European University Institute, the Universities of Sydney, Melbourne, Victoria, and Auckland and the Australian National University, where I was privileged to visit and present it, and also from able research assistant, Andrew Amend, Columbia 2008.  gains very much a work in progress, during changing times.

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whether that finding is replicable. The scientific process is not democratic—no amount of desire for different results can establish them—and inconsistent findings create true controversy only when their methods are of comparable validity.¹

Of course it is equally futile. For science as for law, ‘man’ *cannot* be eliminated. Judgements must be made in inevitable arenas of uncertainty—judgements that will be shaped by human predispositions and heuristics that need hardly correspond to the realities they seek to describe. And beyond these unavoidable human difficulties lie the incentives that in so many contexts twist human behaviours in ways that law seeks to control—greed for profit and lust for power central among them. The issue, then, is somehow giving the objective or perhaps one should just say the open side of scientific endeavour purchase—elevating judgement, suppressing simple will.

The American regulatory landscape has been littered with efforts to distort or suppress information relevant to the responsibilities of federal agencies responsible for protecting health, safety or the environment on the basis of sound science. While these efforts have a long historical pedigree—consider the industrial practices respecting such hazards as silicosis, tobacco and asbestos, or government behaviours in respect of nuclear weapons testing² or the Tuskegee experiment³—recent times have seen them take particular prominence. Drug company failures to, for instance, alert regulators respecting hazards created by their products spread across the pages of two recent books describing a variety of means that have been used in the service of distorted outcomes: creation of research to produce intended outcomes; suppression of unwanted information; discrediting reliable research; interfering with the careers of those who produce unwanted information; and public relations campaigns.⁴ ‘The editors of our best international scientific and medical journals’, one reports, ‘are chagrined by their inability to weed out unreliable research emerging from a funding regime that is increasingly driven by the expectation of future economic gain.’⁵ Within the science community, they suggest, organised insistence on recreating the conditions for honest inquiry will require such measures as mandatory disclosures of all financial interests (conflict of interest reporting) and the development of techniques for data-sharing that permit peer review while diminishing opportunities for harassment and other inappropriate behaviours—along with vigilant self-policing regimes. The situation, one might say, reflects only an ordinary

¹ JD Kraemer, LO Gostin, ‘Science, Politics, and Values: The Politicization of Professional Practice Guidelines’ (2009) 301(6) *Journal of the American Medical Association* 665–67 available at www.jama.ama-assn.org/cgi/content/full/301/6/665.

² www.hss.energy.gov/healthsafety/ohre/roadmap/experiments/index.html; www.historytogo.utah.gov/utah_chapters/utah_today/nucleartestingandthedownwinders.html.

³ www.cdc.gov/tuskegee/timeline.htm.

⁴ TO McGarity and WE Wagner, *Bending Science: How Special Interests Corrupt Public Health Research* (Cambridge MA, Harvard University Press, 2008); D Michaels, *Doubt is Their Product: How Industry’s Assault on Science Threatens Your Health* (Oxford, Oxford University Press, 2008).

⁵ McGarity and Wagner, n 4 above, at 229–30.

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instance of a particular community's need to identify and suppress deviant behaviours that threaten its integrity and values. Theft and fraud, too, are social problems and we develop law and institutions to secure our sense of social honesty. But it is not, of course, simply an intra-community affair. The public consequences of distortion may be quite severe.

Similar alarms were widespread about the Bush administration's treatment of scientific issues. In what one journalist-reporter characterised as 'The Republican War on Science',⁶ battles ranged over such disparate issues as global warming, day-after contraception, endangered species protection, environmental hazard regulation and politicised controls of advisory committee membership. Sixty-two prominent scientists issued a remarkable call for 'Restoring Scientific Integrity in Policy-Making' in February of 2004.⁷ Thousands more signed it subsequently, and the signatories included 52 Nobel laureates, 63 National Medal of Science recipients, and 195 members of the National Academies.⁸ A more recent journalist's account, 'Undermining Science: Suppression and Distortion in the Bush Administration',⁹ suggested that little changed in its wake.

Politics certainly infected these alarms. The Union of Concerned Scientists, that catalysed both the petition and the more recent book, is not a neutral body. Conservative authors and columnists have persuasively pointed to similar episodes in Democrat administrations,¹⁰ and the literature on science, policy and

⁶ C Mooney, *The Republican War on Science* (New York, Basic Books, 2005).

⁷ The text can be found on the website of the Union of Concerned Scientists, www.ucsusa.org/scientific_integrity/abuses_of_science/scientists-sign-on-statement.html.

⁸ www.ucsusa.org/scientific_integrity/solutions/big_picture_solutions/prominent-statement-signatories.html.

⁹ S Shulman, *Undermining Science: Suppression and Distortion in the Bush Administration* (Berkeley and Los Angeles, University of California Press, 2008).

¹⁰ 'For the sake of argument, let's assume that the Bush administration has done all that UCS accuses it of doing. This problem is not particular to Republican administrations—the very linkage of government and science almost guarantees some chicanery. Let's recall the halcyon days of the Clinton administration. In 1993, Princeton University physicist William Happer was fired from the Department of Energy because he disagreed with Vice President Al Gore's views on stratospheric ozone depletion. In 1994, President Bill Clinton rejected the finding from the Embryo Research Panel of the National Institutes of Health which declared that the intentional creation of human embryos for genetic research was ethical. Clinton simply banned any federal funding for such research.

And in 1993, the EPA used a meta-analysis of a number of studies to find that second-hand smoke caused lung cancer in adult non-smokers and serious respiratory problems in children. That may well be, but the EPA had to put its thumb on the scales in order to get the result it wanted. The agency included just 11 out of 30 known studies on second-hand smoke in its meta-analysis, and even then found no increased risk to non-smokers at the 95 percent confidence level that had been the traditional agency standard. So the agency simply moved the confidence level from 95 percent to 90 percent in order to get the result it wanted.

At the time, I talked to a member of the EPA's scientific advisory board, an epidemiologist working at a leading east coast university who requested anonymity. He told me that he knew it was inadvisable to change the confidence level. He didn't oppose the change, though, because he was afraid he would be kicked off the board if he didn't go along. "I wanted to remain relevant to the policy process", he explained. He was also an EPA grant recipient. Ronald Bailey, 'Why government isn't the best place to look for unbiased science', *reasononline*, www.reason.com/news/show/34774.html, (3 March 2004), visited 10 March 2009. And see the NY Times columns and posts to this point

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politics is rich with suggestions that the economic importance and political salience of science and technology issues makes them inevitable.¹¹ As in the case of stem cell research, disputes may often really be about values (eg, the sanctity of human life, understood to begin at conception) rather than science as such, although what one author describes as ‘stealth advocacy’ may often invoke ostensible science in their support.¹²

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One may add that a Republican administration encounters a civil service likely to be much less sympathetic to its preferences than a Democratic one.¹³ Disregard for the work of the civil service could be seen as an understandable reaction to civil servants’ resistance to legitimate political direction.

Still, it is striking that the two administrations prior to that of President Bush, one Republican and one Democratic, found about as many occasions to invoke the Endangered Species Act *each year* as the most recent Bush administration did through its whole term in office¹⁴—and when the latter did invoke it, that was largely under judicial compulsion. Nor had any prior presidency been so marked by the repeated, anguished phenomena of lifetime government scientists resigning jobs that they had not been permitted to serve in integrity, with repeated accounts of muffled reports of scientific views and findings.

President Obama made the issue of ‘restoring scientific integrity’ prominent in his successful political campaign, and an applauded theme of his inaugural address. On 9 March 2009, he issued a memorandum for the heads of executive departments and agencies purporting to address these issues. It appears in full in Appendix A to this chapter. It assigns to the Director of the Office of Science and Technology Policy, the White House office responsible for coordinating science matters in government, the task of developing recommendations that will produce merit-based (ie, not political) appointments, use of scientific methods (including peer review as appropriate) in developing information, heightened transparency, and improved protection for dissidents (‘whistleblowers’). And scepticism whether this was a change in the service of science or of politics immediately followed.¹⁵ What are the tools law can bring to improve the chance

by John Tierney in the New York Times, eg ‘Politicizing Science’, www.tierneylab.blogs.nytimes.com/2009/02/27/politicizing-science, visited 10 March 2009.

¹¹ R Pielke, Jr, *The Honest Broker—Making Sense of Science in Policy and Politics* (Cambridge, Cambridge University Press, 2007); DS Greenberg, *Science, Money and Politics* (Chicago, University of Chicago Press, 2001); S Jasanoff, *The Fifth Branch—Science Advisers as Policymakers* (Cambridge MA, Harvard University Press, 1990).

¹² Pielke, n 11 above.

¹³ See n [redacted] above.

¹⁴ See Sherman, n 9 above, at xii–xiii.

¹⁵ S Stolberg, ‘Obama Puts His Own Spin on Mix of Science with Politics’, NY Times, 9 March 2009; J Tierney, ‘Politics-Free Science?’, www.tierneylab.blogs.nytimes.com/2009/03/09/politics-free-science, visited 10 March 2009. A later report was that:

OSTP Director John Holdren met the 9 July deadline in the presidential memorandum for suggesting how executive agencies should improve their conduct on everything from vetting job

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that sound judgement, 'reason', will prevail, and to diminish the influence of simple will, 'unreason'?

In asking this question, one must be aware of an important lacuna in the characterisation of science earlier quoted. If 'the scientific process is not democratic', it also will rarely be conclusive in those matters of greatest interest to regulators and politicians. No society committed to democracy can afford to ignore the frequently remarked variations between expert and public evaluations of risk. The observable differences in public willingness to accept risks of varying sorts, even when openly and reliably defined, will produce policy outcomes varying from those that straightforward comparison of objective risk levels would suggest. Motorcycle riders will notice no cognitive dissonance as they campaign vigorously against nuclear power. These are issues that might be addressed by education; but while certainly susceptible of political manipulation, they reflect preferences that cannot be discredited. One might distinguish here between political judgements that develop from democratic discussion processes, and political outcomes that are more directly the product of the exercise of simple, and usually covert, will. It is the latter that are the principal concern of this chapter.

SOME EXAMPLES OF WILL OVER JUDGEMENT



This section sketches four examples of settings in which it might be thought 'will' had prevailed over 'judgement', two drawn from American experience and two from abroad.

Treatment regimes for Lyme Disease

The quotation earlier set out was taken from an article in the Journal of the American Medical Association (JAMA) criticising a decision of the Attorney-General of Connecticut to prosecute the Infectious Diseases Society of America (IDSA) for state antitrust violations. In 2006, the IDSA issued updated clinical practice guidelines in 2006 for the diagnosis and treatment of Lyme disease, recommending against the use of longterm antibiotics to treat 'chronic Lyme disease (CLD)'. The IDSA is a private non-governmental organisation (NGO) that formulates recommendations about disease treatment regimens on the basis

applicants to protecting whistleblowers. But the details remain under seal until all relevant agencies have signed off on them.

www.blogs.sciencemag.org/scienceinsider/2009/09/lost-in-space-t.html, dated 1 September 2009 and visited 20 September 2009. In the interim his Office of Science and Technology Policy had conducted and reported numerous innovative programmes in e-government. See generally www.whitehouse.gov/open/, www.whitehouse.gov/open/blog/, and, in particular, www.mixedink.com/OpenGov/, where a government consultation on improving e-government was recently held.

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of available studies. These recommendations are influential on physicians prescribing courses of treatment, and on insurance companies making determinations about coverage. CLD is a label that some use to describe a variety of non-specific symptoms persisting in some Lyme disease sufferers after evidence of bacterial infection has disappeared and for which, frequently, no evidence suggests the etiologic agent of Lyme disease is responsible. IDSA's study, for the authors of the JAMA article demonstrably the product of sound science, had led it to conclude that long-term treatment of these symptoms with antibiotics was ineffective, expensive, and posed the risks associated with long-term antibiotic use. For the International Lyme and Associated Diseases Society (ILADS), however, a CLD advocacy group supported by the manufacturer of the drug used for long-term treatment, and drawing on the work of a committee that included the president of a company that manufactures an alternative Lyme disease diagnostic test and multiple physicians whose practices are listed with the group's patient referral service, these results were anathema. ILADS immediately protested, asserting the superiority of its alternative guidelines; the JAMA article asserts that these guidelines were based on substandard review methods. Within days, the Connecticut Attorney-General launched an investigation, alleging IDSA had violated state antitrust law by excluding differing viewpoints from its guideline creation process and including members who had financial interests in, or ties to, Lyme disease diagnostic and treatment makers. IDSA had disclosed its panel members' potential conflicts of interest in its published guidelines, and the authors of the JAMA article assert that there was no evidence that any conflicts altered the guidelines' content. The committee that created the ILADS guidelines did not disclose the financial interests associated with its guideline document. To avoid exorbitant litigation costs, IDSA was forced to settle the claim and alter its guidelines.

Herceptin and Breast Cancer Treatment in New Zealand

Public subsidisation of medical treatment regimes in New Zealand depends importantly on the judgements reached by Pharmac, a governmental agency whose decisions are grounded in considerations of cost as well as effectiveness. Herceptin is a pharmaceutical that can be effective in treating certain forms of breast cancer, but which itself poses certain health risks if used for a long time, and is quite expensive; a full year's treatment might cost in the range of NZ \$70,000 (depending on the patient's weight). From 2001, Pharmac had listed Herceptin as approved for extended use in the treatment of *metastatic* breast cancers. Subsequently, the question arose whether it should also be approved for treatment of women whose breast cancer had been detected at an earlier stage. In 2006, responding to advice from expert committees that called the drug's cost-effectiveness for these women into question, Pharmac decided not to schedule the drug for that use 'at this time'. To approve the use would have had

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implications for New Zealand's capacity to subsidise other treatment regimes for the full range of diseases. In 2007, responding to broad consultations and to a study suggesting that a nine-week course of treatment with the drug concurrent with chemotherapy showed a level of effectiveness comparable to that which might arise from a full year's treatment, it decided to list the nine-week course of treatment as approved for subsidisation, but did not reopen the one-year question. In April 2008, responding to review sought by breast cancer sufferers wishing the full year option, quite possibly with support from the drug's manufacturer, New Zealand's High Court found that Pharmac had failed to engage in the required level of consultation in reaching its first decision and, while approving the process attending the second decision, concluded that that process had not reopened the one-year question. It directed reconsideration of that question, after full consultation. Pharmac complied, and came to the same conclusion: the benefit of the one-year regimen was too uncertain in relation to its cost. Within the breast cancer community and to the drug's manufacturer, this was of course a highly disappointing outcome, although others understood it as preventing diversion of necessarily limited public funds from other, more promising uses to support health care generally. The matter became an issue in the national elections later that year, and one party promised as part of its campaign to assure full funding. It won, and promptly acted through the Ministry of Health—not Pharmac—to subsidise the full-year regimen.

A Wind Farm in Australia

The Australian Minister for Environment, a member of the Australian Senate, was required to approve the siting of a large wind-farm at Bald Hills, in southern Australia.¹⁶ The siting was locally controversial for reasons grounded in aesthetics and concern over the noise it might produce. And an election was pending, in which a candidate of the minister's party (the minister was himself from a distant riding) had allied himself with the opposition to the farm. The minister refused to approve the application, citing the risk it posed to a critically endangered species of parrot. The parrot was indeed endangered, and wind farms pose unquestionable dangers to migratory birds. But, as has not been unknown in the United States,¹⁷ ostensible concern for the parrot was a stalking horse for local residents unhappy about a projected intrusion on their amenities. When the reports and data on which the minister had relied became available, it proved that few, if any, of the endangered species had ever been seen in the vicinity of the projected wind farm; their population density, to the extent there was any, lay elsewhere, and the major threat to their survival was development and its

¹⁶ This paragraph is based on J Prest, 'The Bald Hills wind farm debacle' in T Bonyhady and P Christoff, (eds), *Climate Law in Australia* (Sydney, Federation Press, 2007).

¹⁷ *Scenic Hudson Preservation Conference v Federal Power Commission*, 354 F2d 608 (2d Cir 1965).

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associated habitat changes. The data suggested that perhaps one parrot would fall to the wind farm every millennium; extinction from other causes was thought likely within 50 years. The availability of this data—and the passage of election day—resulted eventually in a settlement that permitted the wind farm’s construction.

Setting the Secondary Level for Ozone in the United States

In the spring of 2008, the public became aware of disagreements between the Bush White House and the Environmental Protection Administration (EPA) about the level of ozone exposure appropriate for national ambient air quality standards to protect forest growth and other ‘secondary’ targets of protection from harm by air pollution.¹⁸ (‘Primary’ standards are set for public health concerns.) Reflecting the differences they understood between the needs and vulnerabilities of human and forest lungs, the various scientific advisory committees and bureaucratic decision-makers within the EPA had settled on an ozone level marginally differing from the primary standard. It would have been somewhat more stringent than the primary level but also with a more forgiving measurement interval.

These standards are to be set following the public procedures of the Clean Air Act for rule-making, procedures building on but somewhat more stringent than those of the US Administrative Procedure Act  many European countries, the development of similar measures would be described as subsidiary legislation or perhaps ministerial decrees; in the EU, as implementing measures.) Under these procedures as currently understood, the public receives notice of a proposed rule and access to the data and reports underlying it, and any person interested to do so is able to submit additional data and to comment on the proposal; the agency must then explain its decision in some detail and, as already indicated, its reasoning is subject to relatively close scrutiny on judicial review.

The EPA’s Administrator, a politically responsible official comparable in dignity to a Cabinet Secretary and who by statute is given the authority to decide such matters, was prepared to accept and act on the advice he had received from his staff. Before he could do so, however, contemporary arrangements (established by the President for White House coordination and oversight of regulatory activity) required him to seek clearance from an office in the President’s Office of Management and Budget, the Office of Information and Regulatory Affairs (OIRA). OIRA initially sought reconsideration of the matter, suggesting that the primary and secondary standards would most efficiently be identical—set at the somewhat more permissive level already determined for the primary standard. EPA staff generated a response detailing why, in their judgement, the best

¹⁸ J Eilperin, ‘Ozone Rules Weakened at Bush’s Behest; EPA Scrambles To Justify Action’, The Washington Post, 14 March 2008, at A1.

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scientific evidence available about the differing vulnerabilities of humans and forests required differing standards under their statutory responsibilities. The EPA Administrator indicated to the White House, then, that he intended to stand by his staff's judgement. At this point he was directed—told President Bush had decided—that identical standards must be adopted. The Administrator acquiesced.

The resulting blizzard of newspaper stories and congressional inquiries suggested that something untoward had occurred. The relevant statute, placing the responsibility for this decision in the Administrator and not the President, both assumed and required that the decision would be made in accordance with the best available scientific information. Neither the President nor his agent OIRA has the resources or expertise to do good science on such an issue. Moreover, the relevant statute precludes using economic cost/benefit, as such, as a decisional consideration. (While this proposition might seem questionable as a policy matter, it had underlain the US Supreme Court's willingness just a few years earlier to accept the significant law-making authority the statute confers on the EPA's Administrator.¹⁹ Permitting the EPA to make political trade-offs rather than base its actions on ostensibly objective judgements about best science would heighten concerns about the constitutionality of conferring this law-making authority on unelected officials.²⁰ Suspicious were rife that the White House judgement about ozone was animated by raw political concerns for the well-being of favoured industries; or if not that, certainly by the factors of economic cost that the statutes had excluded from the Administrator's consideration. Congressional committees demanded, and the White House adamantly refused to provide, a variety of documentary evidence and testimony on the issue. The standard was issued in the form the White House had insisted upon, and in that form might be subject to judicial review.²¹

¹⁹ *Whitman v American Trucking Ass'ns, Inc* 531 US 457, 475 (2001) ('While Congress need not provide any direction to the EPA regarding the manner in which it is to define "country grain elevators", which are to be exempt from [certain statutory requirements], it must provide substantial guidance on setting air standards that affect the entire national economy').

²⁰ *cf Boreali v Axelrod* 71 NY 2d 1 (1987) (New York's Public Health Council authorised to consider only public health factors in adopting a regulation controlling smoking in public places; it lacks the 'open-ended discretion' to construct 'a regulatory scheme laden with exceptions based solely upon economic and social concerns').

²¹ On 16 September 2009, the EPA Administrator announced that she was reopening the standard, which presumably will moot any review petition that may have been filed. www.yosemite.epa.gov/opa/admpress.nsf/6424ac1caa800aab85257359003f5337/85f90b7711acb0c88525763300617d0d!OpenDocument, visited 20 September 2009.

In a similar Bush administration episode, OIRA delayed for years action on a proposed regulation to protect an endangered species, right whales, from collisions with large boats traveling at speeds that made evasion difficult; the regulation was eventually issued in the form the responsible agency had requested but only after more than a year later than the action times assured by the order creating the OIRA review regime. See Robbie Brown, 'US Requires Ships to Cut Speed in Waters Used by Right Whales', NY Times, 9 October 2008.

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That the back-and-forth became public is due in substantial part to the increasing availability of information about governmental regulatory activities on the Internet. The EPA has been one of the leading agencies in developing public Internet databases associated with its rule-making activities. As a matter of the text, the obligations to expose matters concerned with rule-making appear to be rather slight. Nonetheless, judicial decisions and the realities of the US Freedom of Information Act have resulted in thorough agency exposure of the scientific reports or data on which rule-making decisions may be based, as well as commentary received from outside the agency. The idea that this should happen is uncontroversial, and is strongly voiced in President Obama's recent executive order. To the extent such information is made available and searchable on the Internet, as increasingly it is, citizen monitoring is facilitated. And, responding in part to commitments made in the OIRA mandate, the computerised database for the ozone rule-making quickly included much material revealing the back-and-forth that had occurred. Perhaps a knowledgeable EPA official then suggested to the reporter that he have a look.

THE ROLE OF RULE-MAKING

Each of these examples could be thought to raise the question how the timeliness and internal integrity of government regulatory decision-making can best be promoted. Choices to prosecute (Connecticut), to allocate public funding (New Zealand), to approve an application (Australia) or to adopt a standard (EPA) can all be influenced by factors other than a reasoned judgement about 'best science'. Yet to recognise that this is so, in a democratic society, is not necessarily to condemn that outcome. In the New Zealand case, for example, one might well think that although a large corporation's profit motivations may have influenced the outcome, the spending choice between marginally beneficial breast cancer treatment regimes and other purposes was also a matter that had been contested in the citizenry and was proper for political determination. In this case that decision was openly made in a straightforwardly political way. In the other three cases, one could believe that timely public information about the objective realities underlying the decision could have produced different results. The issues are ones both of procedures employed, and of the place of politics in the determinations made.

The focus of inquiry in the paragraphs following will be on rule-making—the generation of regulations that if valid have the force and effect of statutes—rather than adjudication. Policy issues of broad interest more frequently arise in that context, and there are interesting parallels between the ostensible public procedures for rule-making, as they have developed in the United States, and the paradigmatic methods scientists use to inform their judgements. The 'paper

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hearing' of today's important rule-makings—marked by detailed notice including the availability of underlying data; a seriously taken opportunity for comment; an extensive explanation of agency reasoning in the face of that comment; followed by 'hard look' judicial review—seems remarkably like the scientific method for approaching truths.

The matrix for these paragraphs will be that suggested by President Obama's recent directive on restoring scientific integrity,²² which focuses in turn on selection and retention of candidates; internal procedures including 'well-established scientific processes' such as peer review; and issues of arising out of central government control of rule-making, including transparency, protection for dissidents, and White House relations.

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Selection and retention of candidates

The executive order directs that selection of candidates 'should be based on the candidate's knowledge, credentials, experience, and integrity.' Left off this list of desirable qualities are such typical criteria for political appointment as loyalty and a known predisposition to agree with the President/agency head's policy preferences. One might find room for these qualities in the interstices of 'credentials, experience, and integrity', the language President Obama used in his recent directive; and appraisals of President Obama's own appointments to scientific posts have not been lacking in suggestions that they have been used.²³ Nor can one imagine that persons possessing 'credentials, experience, and integrity' lack political commitments, or predispositions on issues in play in the scientific community respecting which final judgement has yet to be reached. In his short recent book, *The Honest Broker*, Roger Pielke, Jr valuably distinguishes between the kinds of political issues that can be appropriately resolved by reliable inquiry into observable facts—is a tornado approaching? 'tornado politics'—and others that cannot, 'abortion politics'.²⁴ To the extent reliable inquiry cannot produce uncontested answers—very often the case in situations where politicians nonetheless feel required to act (say, respecting climate change)—the engaged scientist is faced with the choice between acting as 'stealth advocate', proceeding on the basis of his or her personal belief or preference, and acting as 'honest broker', stating clearly the alternatives and their associated uncertainties and implications while subduing as best he or she can his or her own priors.

²² Text at n  above.

²³ eg, J Tierney, "Findings: Politics in the Guise of Pure Science," NY Times, 24 February 2009, at D1.

²⁴ Pielke, n 11 above, at 40.

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Committing scientific data-gathering to the civil service?

In speaking to the 'selection of candidates', President Obama is of course addressing the appointees he and his political lieutenants choose and not the members of the permanent civil service. One mechanism that might be thought useful to encourage 'honest broker' behaviour is a definition of function to separate, so far as possible, the responsibility for appraising those issues for which scientific inquiry may be helpful, such as risk, from questions on what to do about such matters once identified. Such a separation could map onto the ostensible distinction in government employment between the permanent civil service, and political appointees who hold office at will and ordinarily change with administrations.

A distinction between risk managers and risk assessors is explicit, for example, in the standard setting activities of the Codex Alimentarius Commission under the aegis of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). This body undertakes setting international standards for food safety to ensure human health protection, in light of the best available scientific data.²⁵ Its documents conceive overall risk analysis as comprised of three functionally separated elements: risk assessment, risk management, and risk communication. The allocation is in the service of creating a zone in which 'scientific integrity' may be assured (risk assessment); another in which political judgements are made and from which guidance and standards emerge (risk management); and a third element of systematic, maximally sustainable transparency that may build public trust (risk communication). Risk assessors are encouraged to identify the data, assumptions and uncertainties bearing on their assessments, and the characteristics of the hazards they identify, and to report their conclusions in a manner permitting peer and public review. Risk managers, taking a range of economic and political factors into account, are to respect 'precaution' and public attitudes towards risk in deciding how best to respond to the assessments thus received; again, their processes and reports should be 'transparent, consistent and fully documented'. Both assessors and managers, while respecting 'legitimate concern to preserve confidentiality', are encouraged to communicate their activities and conclusions with the greatest accuracy and transparency possible, so as to strengthen working relationships and build public trust.

Distinguishing between risk assessors (scientists) and risk managers (the policy-setting overseers to whom they report) might be thought naturally to fit the presuppositions of a permanent civil service working within a framework of political management. That is, one might think, the data gatherers, the risk assessors, are unlikely to have political ambitions or roles; that is the whole point. If initially the impulse to creation of a civil service imagined a body of secretaries

²⁵ Its Working Principles for Risk Analysis for Food Safety for Application by Governments, CAC/GL 62-2007, is attached as Appendix B to this chapter.

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and clerks, and was intended to control the financial and general competence risks of patronage, one may now see it as a means of assuring the best information for government managers—as an instrument for integrity in a different sense. Selection will be made on the basis of objective criteria. Of course some managers are also scientists, the ones whose appointment President Obama was addressing; the relationship between managers and responsible staff in general, ripe with potential for misuse, is addressed below.²⁶

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This intellectual separation is intuitively appealing, and certainly sends useful signals to those minded to heed them. It could be seen to reinforce the ‘honest broker’ vision of scientist function. But as appears amply in the literature, the uncertainties of outcomes and predispositions of analysts confound its reliability.²⁷ ‘Stealth advocacy’ can readily appear at the level of risk assessment, whether or not risk management is identified as a separate task. The scientist who has chosen a civil service career has often sacrificed financially more rewarding avenues, perhaps for competitive reasons suggesting his or her possession of a lesser skill set yet perhaps, instead, in order to serve normative preferences that make public service seem worth that sacrifice. One readily understands the political managers’ fearing this influence, particularly politicians whose attitude toward the project of government is more sceptical than those who choose a lifetime career in it.²⁸ To them, at least, ‘stealth advocacy’ in the memos they receive will appear a significant threat.²⁹

It is unlikely, moreover, that an agency’s civil servants will themselves be able to amass and analyse the data required for risk assessment. Often they will be required to call upon outsiders more expert than themselves, perhaps as ‘special government employees’ or perhaps by requesting or contracting for relevant studies. Now their neutrality may not suffice to satisfy; the Lyme disease example from Connecticut underscores the importance of considering what controls exist over the potential conflicts of interest among outsiders relied on for help in assembling/assessing relevant data. If we are evoking ‘science’ as a rationale, moreover, that entails the values of transparency and openness to refutation. ‘Whether a scientific finding is judged to be accurate is dependent on the quality and rigor of the methods used and whether that finding is replicable.’³⁰

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²⁶ See pp 0  w.

²⁷ eg, Jasanoff, *The Fifth Branch*, n 11 above.

²⁸ ‘A bureaucrat is a Democrat who holds some office that a Republican wants.’ (Alban Barkley, Harry Truman’s Vice President, at the 1948 Democratic Convention, as reported in William Safire, *Safire’s Political Dictionary* (Oxford, Oxford University Press, rev ed 2008) at 90; the quotation is sometimes attributed to President Truman himself, as at www.members.tripod.com/aldems/page20.html, visited 27 April 2009.

²⁹ See AF Wichelman, ‘Administrative Agency Implementation of the National Environmental Policy Act of 1969: A Conceptual Framework for Explaining Differential Response’ (1976) 16 *Natural Resources Journal* 263, on the motivation of government bureaucrats; also discussed in S Taylor, *Making Bureaucracies Think* (Stanford University Press, 1984) and M Painter, *Steering the Modern State* (Sydney, Sydney University Press, 1987).

³⁰ Note  above.

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For reasons such as these, ‘risk assessment’ may be seen as an appropriately public procedure, one that ought to be as contestable and open as the debates over risk management that will follow it. Now the separation virtually disappears. ‘Bending’—that is to say political rather than science-process reasons for decision—may have much to do with the arguments about procedure. Much of the (frequently industrial) pressure to formalise ‘risk assessment’ as an initial, distinct step preparatory to ‘risk management’ can be understood as an instrument of delay. The EPA should not be required to coordinate with the Department of Defense in assessing the ‘toxicity of perchlorate, a component of rocket fuel detected nationally in drinking water, breast milk, and produce’, one activist, consumerist science NGO has argued, as this ‘could mean that the DOD and its contractors are liable for potentially billions of dollars in cleanup costs. The DOD has long sought to weaken any scientific standard that would mandate cleanup of perchlorate contamination.’³¹

Even at what may appear to be the apolitical, civil service level, as a recent fine analysis by Professor David Barron of Harvard,  Deputy Solicitor-General in the US Department of Justice, points out, one of the significant threats to scientific integrity is the much enlarged penetration of ‘political clearances’ into agency bureaucracies. Like OIRA’s regulatory review mechanisms, this trend became pronounced with the administration of Ronald Reagan. Barron reports that:

the number of full-time political appointees serving in the federal government [in policy positions] jumped from 2150 in 1964 to 3687 in 1992. ... These [positions, with 2300 others effectively open to political clearance] ... dwarf, by orders of magnitude, the number of political appointees available to the executive leaders of most European nations. ... The rise in the ranks of economists, engineers, scientists, and lawyers within the bureaucracy itself increases the opportunities for Presidents to remake the bureaucracy in ways that are likely to promote a particular view of regulatory policy.³²

The increasing scope of political clearance for persons having policy responsibilities certainly renders American ‘administration’ more political than might be expected in the strong civil service regimes of many parliamentary democracies. Probably the move in this direction began during the presidency of Jimmy Carter, when a reform of the civil service laws created in the upper echelons of the civil service a Senior Executive Service, those persons responsible for policy direction and other matters involving substantial discretion. In the United States as in European democracies, important federal bureaus, elements perhaps of a

³¹ ‘Scientific Integrity’, a submission of the Union of Concerned Scientists to the public comment files respecting revision of EO 12866, see note and accompanying text below, www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp (visited 12 March 2009), citing Sass J 2004. US Department of Defense and White House working together to avoid cleanup and liability for perchlorate pollution in *International Journal of Occupational and Environmental Health* (abstract) 10:330–34.

³² DJ Barron, ‘From Takeover to Merger: Reforming Administrative Law in an Age of Agency Politicization’ (2008) 76 *George Washington Law Review* 1095, 1123.

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cabinet department, might be under the direction of a senior civil servant, a permanent government employee rather than a political appointee.³³ Perhaps, one would think, smaller numbers of politicians at the top, and a civil service enured to ‘Yes, Minister’ in parliamentary systems make for a rather different picture. It should not be hard to understand the stress such penetration can put on the interface between law and politics.

Scientific integrity at the management level

Turning to the context of risk management: the White House and the political heads of agencies do have significant control over agency management levels. At least three strata of management-level employee can be identified. At the highest level are heads of departments and others whose appointment requires Senate confirmation. Here one can find not only public processes for exploring the merits of appointment, but also the possibility of undertakings to others than the President—that is, to the Senators who confirm—that provide a kind of cover for independent judgement. Second come a much larger number of persons appointed by the President alone, or by the heads of departments, without need for Senate confirmation. Like those whose appointment do require that step, they generally³⁴ serve ‘at will’ but now without either the cover of undertakings to the Senate, or the same basis for belief that their summary dismissal might produce the kinds of political controversy that could make a President hesitate to act. Strikingly, 100 days into the Obama administration the Library of Congress was reporting 177 nominations submitted to Congress for civilian positions,³⁵ but as Professor Barron’s analysis shows, thousands more politically cleared positions exist outside congressional control. Third and finally, there is the Senior Executive Service—lifetime civil servants in senior positions who, since President Carter’s administration, have served in a regime considerably more exposed to reward and punishment for desired and undesired actions than the ordinary civil service. Bureau chiefs may in the past have had the independence of full civil service status and consequent effective room within which to manoeuvre;³⁶ their service today is much more subject to political controls.

Persons living in parliamentary systems built over permanent civil service bodies find the resulting level of politicality in American government astounding. Mutual understandings about the security of lifetime governmental employment are understood to be a major assurance of the integrity of technical assessments.

³³ The classic study of their work, written at about the time of this change, is H Kaufman, *The Administrative Behaviour of Federal Bureau Chiefs* (Washington, The Brookings Institute, 1981).

³⁴ The reservation is made to recognise that Congress has occasionally limited dismissals of persons appointed with and without senatorial confirmation to ‘good cause’. Thankfully, the Supreme Court has not yet had an occasion to address what might constitute ‘cause’ in a legal sense.

³⁵ www.thomas.loc.gov/home/nomis.html, visited 20 September 2009. The number had become 300 by mid-June, 477 by 20 September. By the last date, 328 of the nominations had been confirmed.

³⁶ Kaufman, n 33 above.

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While the creation of inspectors general (serving in this respect a function similar to ombudsmen in European administrations) and whistleblower protections such as President Obama recently re-emphasised provide some protection for scientific integrity, their cover is not complete. Thirty-two years ago, when the author was General Counsel of the US Nuclear Regulatory Commission, its Bureau 'executives' sometimes exercised rigorous control over what they would permit their staff members to tell the Commission about perceived nuclear power risks.³⁷ Nor were Commissioners wholly committed to transparency about possible risks; facing the chance that utilities or equipment manufacturers might bring similar pressures to bear on their personnel to suppress safety concerns they might wish to share with the Commission and aware that their statute affirmatively provided for whistleblower protection, they did not seem eager to encourage 'rat finks'. Such phenomena suggest what must be obvious, that personal integrity and a willingness to subdue personal preferences are irreducible elements of the 'bending' problem.

To the extent the White House controls the selection of agency personnel, the risk that judgements committed to the agency for decision will be made on bases other than those its constitutive statutes commit to it increases. Professor Barron has amply illustrated these risks in his recent article.³⁸ They are perhaps magnified by a quixotic Supreme Court decision taking the position that anyone holding an executive branch office with significant authority to act constitutionally, yet not senatorially confirmed, *must* be appointed by either the President or the head of a cabinet department, narrowly understood.³⁹ And the intensity of senatorial inquiry for those appointments that require confirmation may have at least two consequences promoting White House control. First, by encumbering that process—helping to explain the observable slowness of both nomination (as potential candidates are vetted to avoid embarrassments) and confirmation—it produces enduring *agency* vacancies in ostensible political positions,⁴⁰ inviting direct White House engagement in the interim. Second, the same costs rationally lead the President to prefer locating responsibility, to the extent he can, in persons he can place quickly in a position to act, and who are not required to answer Senate inquiry, perhaps creating a conflicting sense of political obligation. It is easy to understand the increasing use of White House 'czars' in this light.

While in parliamentary systems it may be natural for the prime minister to see himself as a persuader/conciliator open to constructive dialogue and shared

³⁷ Not without chastening consequence; one suppressed employee went to the CBS programme, 'Sixty Minutes' with his concerns, producing both public scandal and congressional hearings that consumed a great deal of the time the Commissioners might otherwise have had for regulatory matters.

³⁸ N 32 above.

³⁹ *Freytag v Commissioner*, 501 US 868 (1991).

⁴⁰ Seven months into the Obama Administration, just 43% of more than 500 positions requiring Senate confirmation had been filled. See P Baker, 'Obama Team Lacking Most of Top Players', NY Times, 24 August 2009, at A1.

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responsibility, the ‘unitary executive’ idea, pursued to its theoretical limits, has other implications. In recent writings, Robert Post has pointed to the differences from the perspective of democracy between political conceptions that are centered on loyalty—you are with me or you are my enemy—and others that welcome disagreement, preferring a team of rivals from which judgements can emerge by a process of constructive conversation.⁴¹ In the Bush administration, it often appeared that the first duties of civilian heads of departments, like generals of the Army, were thought to be loyalty and obedience—a perspective that may conduce to efficiency in executive governance but offers less promise to democracy. For President Harry S Truman, who regarded the President’s office as one of conciliation and persuasion, ‘Whenever you have an efficient government you have a dictatorship.’⁴² In the first months of the Obama administration, some disposition to hear all sides—to enlist ‘honest brokers’—might be suggested by the President’s appointment of his principal political opponent to be his Secretary of State, and his reputation as a person committed to hearing all sides. His nomination of a former colleague, Professor Cass Sunstein, to head the office most directly concerned with domestic regulation, the Office of Information and Regulatory Analysis (OIRA) in the Office of Management and Budget (OMB), would put in that important post an academic whose recent writings have repeatedly stressed the importance of hearing all sides for sound decision.⁴³ Yet an ‘Inside Account’ of the President Bush’s controversial decision on stem cell research persuasively portrays it, too, as the product of intense internal dialogue;⁴⁴ and President Obama’s undertakings of increased transparency, unsurprisingly, have yet to result in significant public exposure of advice he has received from within the executive branch.⁴⁵ Truman again:

 President cannot function without advisers or without advice, written or oral. But just as soon as he is required to show what kind of advice he has had, who said what to him, or what kind of records he has, the advice received will be worthless.⁴⁶

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⁴¹ See, eg, R Post, ‘Theorizing Disagreement: Re-Conceiving the Relationship between Law and Politics’ *California Law Review* (forthcoming), *Yale Law School Public Law & Legal Theory Research Paper No. 195*, available at www.papers.ssrn.com/abstract #1434103.

⁴² Harry S Truman, *Lecture at Columbia University, 28 April 1959*, www.quotationspage.com/quote/27058.html, visited 21 April 2009.

⁴³ See CR Sunstein, ‘The Empiricist Strikes Back’, *The New Republic*, 10 September 2008, at 9; T Kuran and CR Sunstein, ‘Availability Cascades and Risk Regulation’ (1999) 51 *Stanford Law Review* 683.

⁴⁴ J Lefkowitz, ‘Stem Cells and the President—An Inside Account’, *Commentary* (January 2008), www.commentarymagazine.com/viewarticle.cfm/stem-cells-and-the-president-br-an-inside-account-11024?page=all (visited 3 June 2009).

⁴⁵ Prominent among a number of public consultations begun by the Obama administration within its first 100 days in office was one in connection with its reexamination of Executive Order 12286, discussed further below. See text below accompanying n .

⁴⁶ H Truman, *Memoirs: Years of Trial and Hope* (New York, Garden City, 1956).

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Further discussion of the transparency side of these issues will be found below, as well as an examination of the White House control mechanisms.⁴⁷ But in concluding a discussion of the appointments issues, as such, some mention is warranted of the resistance of recent Presidents to congressional instructions about appointment qualifications; these Presidents have asserted an essentially constitutional right to propose whomever they wanted. President Clinton appended such a statement on signing a bill that, inter alia, sought to limit the pool of persons he might nominate for US Trade Representative to avoid arguable conflicts of interest. In the wake of the Katrina disaster and the deficiencies in Federal Emergency Management Administration (FEMA) management it revealed, Congress passed statutes requiring that the person appointed to head FEMA be a person experienced in the management of complex institutions and disaster management.⁴⁸ In a later statute, it directed that appointees to high office in the United States Postal Commission have similar experience-related backgrounds.⁴⁹ In signing the lengthy statutes including these provisions into law, President George W Bush identified these two provisions in particular, as against many he accepted, as unconstitutional infringements of his authority to nominate or appoint anyone he chose.⁵⁰ The obverse of congressional creation of appointments limits suggesting commitments to, for example, professional integrity is that openness to political direction in the face of those commitments can be highly valued.

One area of personnel control that has long been thought important, in science as in politics, is the subduing of personal financial advantage—not power, now, so much as greed. Both formal conflict of interest requirements and attention to the loyalties likely to persevere from prior activities and commitments operate here. The presuppositions of a civil service that invites transition between public and private life, as the American one does, at both leadership and staff levels, creates inevitable tensions. These are dealt with, but imperfectly, by financial controls and by restrictions on ‘revolving door’ service. One President appoints a construction executive to head the Occupational Safety and Health Administration; another, an industrial safety professional with union connections. Each on leaving office may return to a post similar to that from which he or she came; either may be preferable to appointing a skilled administrator who is inexperienced about issues of workplace safety; both may return to

⁴⁷ See pp 

⁴⁸ Department of Homeland Security Appropriations Act 2007 § 611(11), 6 USC § 313.

⁴⁹ Postal Accountability and Enhancement Act 2006 § 501, 39 USC § 202.

⁵⁰ Statement by President George W Bush Upon Signing HR 5441, 2006 USCCAN S49, S52 (4 October 2006) (‘[the statute] purports to limit the qualifications of the pool of persons from whom the President may select the appointee in a manner that rules out a large portion of those persons best qualified by experience and knowledge to fill the office. The executive branch shall construe [section 611] in a manner consistent with the Appointments Clause of the Constitution.’); Statement by President George W Bush Upon Signing HR 6407, 2006 USCCAN S76 (20 December 2006) (making an almost identical statement).

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private life with increased skills and understanding that in fact serve to aid their clients' attention to industrial safety realities. And for both, questions can be raised about the 'objectivity' of their attention to programmatic issues.

Conflict of interest regulation and revolving-door control have been recurrent issues in the United States. President Obama made strong commitments to avoiding appointments questionable on such grounds, yet some of his initial designees withdrew in embarrassment after compromising connections or lapses came to light. Others did not and, as with Secretary of the Treasury Geithner, it is not surprising that appointees bring with them prior commitments or experience that seem likely to influence their judgement. Attention to such issues is perhaps easier, and more readily regularised, at lower levels—as, for example, assurance of balance and lack of conflict in the advisory panels that work with the Food and Drug Administration or the EPA.⁵¹ The literature is replete with examples of settings in which these efforts have not been successful and, indeed, it may be hard even in the academy to find a pharmacological expert who has not had financial dealings with the drug industry. The FAO-WHO Codex Alimentarius process already mentioned commits to having experts involved in risk assessment publicly known, transparently selected, and free of potentially disabling conflicts of interest. The FAO questionnaire on the subject explores in considerable detail, for individuals and also their families and business connections, a wide range of financial and other interests that could raise such questions—seeking explanations where potential conflicts arise, presuming consent to disclosure of the document, and suggesting that disqualification may occur if disclosure is refused.⁵² But with disclosure, appointments are not disqualified.

Procedures

Incentives for integrity might also be found in objectivised, procedural controls over rule-making. We can briefly mention two—judicial review of the outcomes, and peer review of the relevant science. In doing so, however, one must bear in mind the caution suggested by the noted American scholar Jerry Mashaw, writing about procedural choices in the context of administrative adjudications affecting individual rights. Mashaw persuasively argued the point that there is no 'best' answer. He identified three perspectives from which this question could be approached: individual fairness, affording maximum attention to the process claims of the individuals whose rights are at stake; professional integrity, considering *both* the arguable contributions made to sound decisions by the professional commitments of the deciders *and* the possible interference with these

⁵¹ See, eg, McGarity and Wagner, n 4 above, at 181–203.

⁵² The questionnaire is attached as Appendix C to this chapter.

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contributions that could be created by procedural details;⁵³ and bureaucratic rationality, which would value the confinement of likely error to cases ‘on the borderline’ and efficiency—low cost in relation to the issues to be determined.

If these hypotheses are correct, then it may also follow that the best system of administrative adjudication may be the one most open to criticism. A compromise that seeks to preserve the values and to respond at once to the insights of all of these conceptions of justice will, from the perspective of each separate conception, appear incoherent and unjust. The best system of administrative adjudication that can be devised may fall tragically short of our inconsistent ideals.⁵⁴

And, of course, procedural requirements may not only contribute to more accurate or efficient, or fair outcomes. They may also provide ‘handles’ that participants eager to add delay or expense to government determinations can use to achieve that. As long-time American Congressman John Dingell is reported once to have observed, ‘If you let me write the *procedure*, and I let you write the substance, I’ll screw you *every time*.’⁵⁵ Many believe that the notorious slowness and infrequency of rule-making on issues of occupational safety and health is the product of industrial success in securing cumbersome and expensive procedural requirements in a law whose purpose of improving worker safety they could not directly oppose. Claims to improving fairness and accuracy were a different matter.

So the same kinds of trade-offs as Mashaw remarked for the setting of adjudication may be implicit in providing procedures for standard-setting. Even if we start with the proposition that the standards to be set should reflect as is best possible the state of scientific knowledge, we can identify significant elements that will influence the timeliness, accuracy and acceptability of the outcomes. Rule-making in American law is a public procedure, with agencies statutorily required to solicit public comment on any proposal before acting on it, and to explain their reasoning in response to comments and other materials when they do act. American case law has largely established propositions central to the language in President Obama’s recent executive order providing that:

(1) ... (c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;

⁵³ Examples might be teachers or doctors, whose professional commitments have often been relied upon. In the welfare context, the proceduralisation of welfare administration in the wake of *Goldberg v Kelly*, 397 US 254 (1970), brought about a shift in hiring from social workers, professionally committed to the wellbeing of their clients, to caseworkers with an eye to the bottom line. See WH Simon, ‘Legality, Bureaucracy, and Class in the Welfare System’ (1983) 92 *Yale Law Journal* 1198.

⁵⁴ JL Mashaw, *Bureaucratic Justice: Managing Social Security Disability Claims* (New Haven, Yale University Press, 1983).

⁵⁵ M Foley and JE Owens, *Congress and the Presidency: Institutional Politics in a Separated System* (Manchester, Manchester University Press, 1996) (emphases added).

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(d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions.

(e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised ...

And as long as three decades ago, a thoughtful writer celebrated the proposition that judicial review of rule-makings, requiring what our courts have called a 'hard look' at matters in controversy, armed those within an agency who cared about reasoned decision-making (ie, acts of judgement) with a weapon with which to influence those who did not (ie, prefer acts of will).⁵⁶ The other side of this, however, has been the plaint recurrent in the American literature that the 'hard look' has produced ossification—by making it too costly for agencies to produce regulations, and providing the opponents of warranted regulation with too many tools by which to delay or obstruct it.⁵⁷

Perhaps nowhere in American administrative law have ossification concerns been voiced more loudly than in connection with the issues of peer review and information quality—both issues on which the executive order appears to make commitments. Does peer review add another step to what is already a time-consuming, resource-expensive process? In the realm of 'pure science' (or review for publication in science journals), peer review might be characterised as merely the process that happens (assessments and efforts at replication that conduce to validity), and the passage of time is not so relevant as a factor. Add financial or power consequences to truth-seeking, and social consequences to delay, however, and matters become considerably more complex. If it is to be conducted outside government (that is, using scientists whose connection with public service is no more than as a special employee), can adequate assurances be attained that the reviewing peers will not be interested ones? The Bush administration's efforts to put peer review mechanisms in place were widely criticised for their perceived tendencies to produce delay and to arm regulatory opponents without notably improving regulatory outcomes. A so-called 'Information Quality Act' was inserted by stealth in an omnibus budget statute during the Bush administration, and seen by many to have similar tendencies. 'More study is required' is notoriously an obstacle to action—appropriate at times, but readily wielded in a wider range of circumstances.

One does not too readily find enforceably mandated procedures like the American ones for the adoption of regulatory measures in other political systems. The European Union engages in advanced public consultations about proposed

⁵⁶ WF Pedersen, Jr, *Formal Records and Informal Rulemaking* (1975) 85 *Yale LJ* 38, 59–60.

⁵⁷ A sceptical note has recently been sounded about these claims by S Shapiro, 'Explaining Ossification: An Examination of the Time to Finish Rulemakings' (11 August 2009). Available at SSRN: www.ssrn.com/abstract=1447337 (Visited 20 September 2009).

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legislative actions; for subsidiary legislation corresponding to American rule-making, however, it deploys the somewhat obscure process of comitology, which lacks similar commitments.⁵⁸ In the development of Codex Alimentarius standards, FAO-WHO employs a process resembling American notice and comment rule-making, with some exposure of data, opportunities for comment by interested persons, and an ostensible commitment to objective, science-based judgement. Adoption, however, is political, by agreement of the Member States; the extent to which transparency is actually achieved, by documents or through the Internet, appears uncertain (perhaps especially at later stages); and it does not appear there is any objectivised test of the reasoning that may be employed. In parliamentary democracies the responsibility of ministers to the Parliament is often, if not invariably, accepted as a sufficient basis for their exercise of rule-making powers.

Recent, broadly grounded studies by members of the science community have emphasised the positive contributions of embrative participatory processes to the quality as well as the acceptability of judgements made in contexts like these.⁵⁹ Building on the dominant ethic of scientific inquiry—the full reporting of approaches, data, reasoning and results, with open acknowledgment of and attempts to frame uncertainties—these studies stress transparency and candour as root values of the iterative processes they imagine. Of course certain realities intrude when translating the conditions of scientific inquiry to the world of government action. Securing the cooperation of commercial participants, often essential, may depend on effective capacity to assure them that information they provide will not be revealed to competitors or in other respects imperil their interests. Government actors will not be disposed or able to await the definitive resolution of all issues in the face of needs for action, not merely knowledge. Not every participant in a process will be motivated simply by the pursuit of accurate understanding. Concerns for efficiency, and for protection against manipulative uses of opportunities afforded for participation, have consequent force.

A further complication is introduced by the fact, frequently remarked, that the public simply does not evaluate risks the same way experts do. New Zealand's experience with Herceptin might be taken as an exemplar of this problem: where administrators deemed the benefits of a full year of treatment too uncertain to justify diverting public funds, yet the public (whose funds they were) voted in favour of the diversion. In a democratic society, such electoral choices and the value judgements they reflect cannot be dismissed.

⁵⁸ See generally PL Strauss *et al*, *Administrative Law of the European Union: Rulemaking* (Chicago, American Bar Association, 2008).

⁵⁹ T Dietz and P Stern (eds), *Public Participation in Environmental Assessment and Decision Making* (Washington, National Research Council, 2008); J Chilvers, 'Deliberating Competence: Theoretical and Practitioner Perspectives on Effective Participatory Appraisal Practice' (2008) 33 *Science, Technology & Human Values* 421.

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Central government controls and politics

Oversight or Control?

Recent years have seen both a significant expansion of agency control mechanisms in the White House itself and, as mentioned above,⁶⁰ much enlarged penetration of ‘political clearances’ into agency bureaucracies. While the controls centered in OIRA, discussed further below, have attracted the most scholarly and congressional attention, Lisa Bressman and Michael Vandenbergh’s groundbreaking account of the EPA-White House interface from the perspective of EPA political appointees dramatically illustrates the number of White House voices (in both Republican and Democratic administrations) purporting to exercise ‘presidential control’.⁶¹ President Obama’s appointments to White House positions—for example, a former EPA administrator, Carol Browner, to a new position as White House Coordinator of Energy and Climate Policy, ‘climate czarina’—suggests that this reality may persevere. The prompt annulment of President Bush’s Executive Order 13422, on the other hand, withdrew certain personnel requirements for responsibility *within* agencies that might have been seen as additional political controls.⁶²

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An entirely separate issue, and the one that initially catalysed this writing, concerns the place of political controls, and perhaps especially centralised executive political controls, over the outcomes of standard setting activities. American arrangements for the allocation of executive authority typically place responsibility for science-based decision-making in civil service-dominated agencies rather than the political White House. When the legislature has empowered a particular organ of government to create regulations—subsidiary norms—to carry forward a statutory scheme that imagines technical or scientific judgements being made, what is the appropriate reach of centralised executive oversight or control?

Consider the ozone regulation episode described above. The bureaucratic structures President Bush employed in interacting with EPA did not originate with him, but have been steadily developed by American presidents at least since the administration of Richard Nixon, most notably by Ronald Reagan and Bill Clinton.⁶³ Their current expression is in Executive Order 12,866, an order initially created by President Clinton and then somewhat modified by President Bush. The order, in basic outline, creates three stages for agency consultation with the White House during rule-making: first, consultation with the White House

⁶⁰ See text accompanying n  ove.

⁶¹ LS Bressman and MP Vandenbergh, *Inside the Administrative State: A Critical Look at the Practice of Presidential Control* (2006) 105 *Michigan Law Review* 47, 47–52.

⁶² Exec Order No 13,422, 72 Fed Reg 2763 (23 January 2007), essentially required every agency to place control over its rule-making operations in the hands, not of the agency head, but of a staffer directly responsible to the White House.

⁶³ Such a regime was first given formal public shape by President Jimmy Carter (Exec Order 12,044); precursors can be found in the presidencies of Richard Nixon and Gerald Ford.

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about their rule-making priorities (the ‘regulatory plan’, which is published annually in advance of any particular proposals); and then draft and final analyses of particular rules to be proposed and perhaps adopted in carrying out the plan. For the latter stages, the order directs agencies, to the extent consistent with law, to engage in structured analyses of the projected costs and benefits of rule-making proposals, assessing the projected costs and benefits of alternative approaches and choosing that policy which maximises benefits in relation to costs and in other respects conforms to presidential policy preferences. The intensity of this effort and of OIRA’s supervision of it is to vary with the importance of the rule; the greatest effort is required for proposals likely to add \$100 million or more annually to industrial costs or in other respects have a major economic impact.

Although not statutory, the existence and general shape of this regime have been accepted by Congress, which has passed several statutes assuming its existence and continuation, and by the academic community. Rule-making is understood to be too important to national well-being for there not to be a strong central voice and regime for coordination and settlement of interagency dispute. Through the Clinton administration at least, the disputes that have arisen about it could be characterised as marginal: the nature and extent of its transparency; the precise nature of the inquiry to be conducted; the balance OIRA should strike between supervision of agency processes in general and detailed attention to particular proposals; and the threshold beneath which only superficial OIRA engagement is appropriate.⁶⁴

Probably the most important criticism has been that, as administered, Executive Order 12866 has too often proved not to be a neutral device, but rather a deregulatory device—a source of delay and diversion, a pressure point for reduction of burdens and not actions to protect the public. A narrow focus on monetised ‘costs’ and ‘benefits’, in relation only to regulatory actions agencies have in fact proposed (and not, then, to their priority choices), has largely been responsible for that. But beyond this is the possibility that presidential involvement has led to decision based on considerations other than those the agencies explain in their statutorily required ‘statement of basis and purpose’.

In the American context, the controversy about the chief executive’s engagement with rule-making has a number of elements, some of which are doubtless (and perhaps happily) unique to it and may be seen to illustrate ongoing disputes about the nature and extent of the American President’s authority in relation to the decisions of domestic government. Our Constitution vests our President, our one elected executive official, with ‘the Executive power’, in a largely undefined way. Does that entitle him to *decide* every matter the Congress may delegate to

⁶⁴ OIRA will doubtless remain a small office, and one lacking the expertise to be found in the operating agencies. This makes it important that effort be focused on the most important rule-makings, and that it be prompt. No more than a few hundred rules annually, as such, should be in strong review.

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cabinet Departments and other governmental agencies? Or is he merely to *oversee* their doing so, accepting that ultimate legal responsibility for action has been placed in them and that his authority is limited to persuasion, to replacing officers whose decisions displease him, and the like?

I have discussed this question at length elsewhere.⁶⁵ In a nutshell, my view is that control and influence are different matters. As our one elected executive official with a constitutionally defined active role, the President is certainly entitled to try to influence agencies; he would be shirking if he did not do so. He enjoys constitutional authority to demand the ‘Opinion, in writing’ from the leadership of executive departments on any matter Congress has assigned to them.⁶⁶ Certainly this supposes that, once informed of their opinion, he will have a chance at least to reason with them on any matter Congress has assigned to them (that is, their ‘Duties’, to which the same constitutional text also refers). For me, this must include the so-called independent regulatory commissions as well as the cabinet departments. And where responsibilities are shared among several agencies—to take an example I am a bit familiar with, radiation exposure protections, which concern the Nuclear Regulatory Commission, EPA, Occupational Safety and Health Administration, the Department of Defense, the Department of Energy, the Department of Transportation (hazmats) and probably others—coordination must be part of what he has to do. He should have staff to help him with this, a matter of particular importance where multiple agencies are involved.

Control, in my judgement, is an entirely different matter. Congress has placed decisional responsibility in the EPA, say, not in the President. That placement, no less than the placing of the Forest Service in the Department of Agriculture and National Parks in the Department of the Interior, is a part of the law to whose faithful execution the President has undertaken to see. He is not assuring the faithful execution of the law if he purports to assign decisional responsibility to a place Congress has not put it, or takes on himself decisional responsibility for a matter Congress has delegated to someone else.

This is not to say that presidential supervision of rule-making is per se inappropriate. It seems at least possible that the new administration will pay more disciplined attention than its predecessors have to the first, priority-setting stage of the executive order process. Priority planning has been a part of the executive order at least since the second Reagan administration, but it has never been seriously used, so far as I have been able to tell. Strikingly, for example, a recent Government Accountability Office (GAO) Report,⁶⁷ while paying detailed

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⁶⁵ PL Strauss, ‘Overseer or “The Decider”?’ *The President in Administrative Law* (2007) 75 *Geo Wash L Rev* 695.

⁶⁶ US Const art II, § 2, cl 1 (The President ‘may require the Opinion, in writing, of the principal Officer in each of the executive Departments, upon any subject relating to the *Duties of their respective Offices*.’) (emphasis added).

⁶⁷ See n. 10 below.

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attention to agency decision processes throughout the initiation and development of rule-makings, essentially ignores the formation of the regulatory plan.  conversations with agencies about their priorities—where the President believes it is important for them to put their effort—is in my judgement far more likely to be effective in improving government performance and administration than retrospectively checking sums on a series of particular rules. So also, engagement with agencies in how they structure their internal processes to promote sound and efficient analysis and decision, downplaying retrospective analysis of what is already well under way. Retrospective analysis threatens, and has been used to secure, considerable delay of initiatives already established as important priorities. And an emphasis on the regulatory plan element may also increase political responsibility *within* agencies. Chris DeMuth, the progenitor of the regulatory plan element, rationalised it as a way to give the political heads within agencies a mechanism for engaging with their staff at the outset of rule-makings, rather than also find themselves caught in retrospective exercises with effective *faits accomplis* perpetuated by staff.

Further, there are certain questions (foreign policy issues for example) as to which there is ‘no law to apply’, as the courts have said, and federal officials are merely the organs to express presidential will. Chief Justice Marshall famously addressed this setting in *Marbury v Madison*.⁶⁸ But where legality is central to our very tolerance of governmental authority, as it is for rule-making decisions like those of the EPA, then in my judgement our President’s role under the laws, in a government of laws, requires him to respect Congress’s placement of duties where Congress has placed them. When the EPA is authorised to adopt rules, it is the head of the EPA who has the responsibility to decide those matters. The President’s place is one of oversight, not decision, making sure that he or she does that well. Which of course includes the agency head’s acting only on the basis of those factors Congress has made relevant to his or her decision—precisely the issue President Bush’s intervention on ozone appeared to compromise.⁶⁹ Of course consultation can often result in pressures, the substitution of judgement in fact. To turn from the presidency for the moment, the courts, too, know that they are responsible to review agency action (oversight) but are not to substitute their own judgements (decision); yet this does not keep them from doing things on occasion that to the observer seem like substitution. The important thing is the attitude—that agencies know what their responsibilities are, that courts are aware that they, like Presidents, are not supposed to substitute judgement, and that onlookers like myself can point to departures and cry ‘Shame!’

⁶⁸ *Marbury v Madison* 5 US (1 Cranch) 137 (1803): an official obliged ‘to conform precisely to the will of the President,’ Marshall wrote, ‘is the mere organ by whom that will is communicated. The acts of such an officer, as an officer, can never be examinable by the courts. ... The province of the court is, solely, to decide on the rights of individuals, not to enquire how the executive, or executive officers, perform duties in which they have a discretion. Questions, in their nature political, or which are, by the constitution and laws, submitted to the executive, can never be made in this court.’

⁶⁹ *Massachusetts v EPA* 549 US 497, 533 (2007).

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My casebook colleague Todd Rakoff, reading an early draft of this chapter, remarked that it might be useful to note ‘that our parties—or those that have a chance of coming to power—are based on very broad coalitions, such that each represents (albeit to differing degrees) most of the views to be found on public policy.’ Over the years American political parties have enforced much less rigorous discipline, particularly in the Congress, than the parties of parliamentary democracies often deploy. Absent much party discipline or feeling that it ought to prevail, the result is to make even executive administration quite diverse. As President Harry Truman famously remarked when President Eisenhower, a former general, had been elected to succeed him, ‘He’ll sit here ... and he’ll say, “Do this! Do that!” And nothing will happen. Poor Ike—it won’t be a bit like the Army. He’ll find it very frustrating.’⁷⁰ If presidential power is understood as the power to *persuade*—if those with whom he interacts understand that duties lie with them, that loyalty is not the *primum bonum* of holding executive office, and that the diversity of political view within their party creates wiggle room for them in performing their duties—then one might argue that the 2,500 or so presidential administrative appointments made without the benefit of Senate confirmation will still predictably represent, in some crude but real sense, the disparate views of a majority of the population. Introduce the emphasis on loyalty and effective party discipline that has characterised the Republican party in recent years, in Congress as well as in the White House, and this reassurance disappears.⁷¹ The governing ethic of those taking the ‘strong unitary executive’ view is that the first duties of civilian heads of departments, like generals of the Army, are loyalty and obedience. Recall Truman’s quip: ‘Whenever you have an efficient government you have a dictatorship.’⁷²

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Transparency, Accountability, and the Honest Broker

Knowledge of what White House officials are doing is surely a prerequisite for presidential political responsibility, indeed for arming political response. Fortunately, there is at least some reason to believe the present executive order regime can facilitate the necessary watchdogging. The involvement of OIRA is perhaps the most regular and (although not completely) transparent means by which political officials may succeed in influencing decisions ostensibly committed to bureaucrats instructed to act on the basis of objective data and limited, stated considerations.⁷³ As noted previously, that OIRA’s interventions in the ozone

⁷⁰ R Neustadt, *Presidential Power and the Modern President* (New York, Free Press, 1991).

⁷¹ *cf* the decision of Senator Arlen Specter, a long-time moderate Republican from Pennsylvania, to switch parties, which appears at least in part to have been motivated by the prospect of strong opposition within his party in a coming election, given his moderate views.

⁷² See n 70  ove.

⁷³ Accounts of Vice President Dick Cheney’s behaviour in office, eg, have included his repeated forceful and undisclosed interventions on a question concerning the amount of water (that might otherwise be used by farmers for irrigation) to be released from a single western dam in order to

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rule-making became public owes something to precommitments it had made. These were made as part of the political price exacted by previous Congresses for accepting the role Presidents had established for it; the disclosures also had their source in bureaucratic initiative. And the ensuing proceedings, congressional and judicial, as well as the fact of a searchable Internet database, reflect possible controls on such interventions in the American context. President Obama's apparent taste for other central offices with oversight responsibilities⁷⁴ suggests a possible need to generalise these controls.

Indeed, new scholarship highlights a remarkable gap in the public record. In a piece appearing on SSRN,⁷⁵ Professor Nina Mendelson persuasively analyses the opaque disconnect between agency reasoning and White House influence.

 reading in and Westlaw searching of Federal Register statements ... has yet to reveal an agency stating that executive supervision has resulted in it revising its final decision, choosing one option over another, or electing one interpretation of a statute as opposed to another.⁷⁶

A recently published GAO study of rule development and OIRA reviews suggests that—as proved out in the Ozone case—presidential fingerprints are more readily to be found in rule-making dockets than statements of basis and purpose; the study also suggests considerable deficiencies in the transparency of the present process.⁷⁷

Perhaps our President's promises of transparency will change all this—lift the veil of privilege, expose the influence of values on decision as Professor Mendelson urges. Or perhaps not. The public alarm over President Bush's apparent use of the EO 12,866 procedures to 'bend science' led President Obama, at the very outset of his administration, to announce a sweeping reconsideration of the practice. Without awaiting further public input, he revoked changes that President Bush had made in the order, that obscured the role of the Vice President, required the designation in each agency of political officers directly responsible to him to control rule-making, and expanded the reach and intensity of OIRA's review. This effectively restored it to the shape it had had during the Clinton administration—but in that administration as well the order did not lack critics

protect an endangered species of fish living in the river on which the dam was situated. Under the statute, wisely or not, the farmers' needs were not a relevant consideration; rather, the decision was to be based on a scientific assessment of the survival needs of the endangered species. J Becker and B Gellman, 'Leaving No Tracks', *The Washington Post*, 27 June 2007, at A1.

⁷⁴ See the text above, following . Recent commentary on these offices, strongly suggesting their deficiencies in transparency alongside their legitimacy for securing coordination among the variety of agencies that may be charged with particular elements of a problem, appears in Czar Talk, www.ombwatch.org/node/10403, visited 21 September 2009.

⁷⁵  Mendelson, 'Including "Political" Reasons in Agency Decision Making', www.papers.ssrn.com/Ssrn/papers.cfm?abstract_id=1359287, visited 27 March 2009.

⁷⁶  n 3.

⁷⁷  GAO, Report to the Chairman, Committee on Oversight and Government Reform, House of Representatives, 'Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB Regulatory Reviews', GAO-09-205, April 2009.

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of its politicising and delay-promoting possibilities. Perhaps in consequence, President Obama has invited public as well as agency engagement with the question, how the order should be revised. As of 20 April, 183 public comments or meetings had been memorialised on the White House website,⁷⁸ reflecting the wide range of views held on the matter.

Strikingly, and perhaps an indicator of the sensitivity about exposing internal executive branch communications that will doubtless complicate President Obama's commitment to transparency, there is not a single comment from a public agency; two meetings are mentioned, but in each case only the names of agency attendees are given.

Indeed, one kind of issue about presidential control with proven implications for 'science-bending' concerns presidential control over executive branch communications with Congress, a sort of control likely to be much harder to achieve where ministers are members of parliament who must be prepared to respond, with their own re-electability on the line, in free flowing 'question time'. Transparency, and all the contributions to 'honest brokering' and effective democracy through the 'marketplace of ideas' that go with it, are impaired if the President takes the position that communications with Congress or the public must be pre-cleared politically. One notorious example during the Bush administration was the suppression of projections concerning the cost of certain health-care measures.

Some White House controls are of long-standing, however. During my tenure as General Counsel of the US Nuclear Regulatory Commission some three decades ago, the Office of Management and Budget was already 'coordinating' (ie, pre-clearing) communications and testimony to Congress about legislative proposals and budgetary matters. The Commission's nominal independence (it was of course an element of the executive branch, but its statutes provided explicitly for direct communication) softened these controls; but, as noted above,⁷⁹ within the Commission itself, Bureau 'executives' sometimes kept their staffers on a tight leash in terms of what the latter were permitted to tell the Commission about perceived nuclear energy risks. And similar pressures might be brought to bear on utility personnel to suppress safety concerns they might wish to share with the Commission. Such 'bending' did not conduce to public protection.

The legal basis for sweeping presidential control over communication by others in the executive branch, if not its political reality, can be questioned. To the extent the American Constitution speaks to the matter at all, it merely permits the President to recommend to the Congress such legislation as he regards as expedient. Citizens of parliamentary democracies, inured to the powers of their prime minister over legislative business, will easily grasp the weakness of this

⁷⁸ www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp, visited 10 September 2009.

⁷⁹ See n  ove and accompanying text.

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provision, which addresses only presidential initiative and does not even suggest that a presidential suggestion must become legislative business. For that to happen, some member of Congress must introduce a bill, whose language the President cannot legally control. There is nothing here about keeping others from making any recommendations they might like. Nonetheless, as indicated, Presidents have long asserted the right to sit astride any such communications, at least outside the 'independent regulatory commission' context.

The strong Bush (and Reagan) administration theories of the 'unitary executive' can be found in a memorandum entitled 'Authority of Agency Officials to Prohibit Employees from Providing Information to Congress', explaining the withholding of projections of health programme costs from Congress, following a discussion properly reciting the Clinton, etc, invocation of executive privilege in more conventional contexts:

The foregoing discussion does not mean that an agency's right to supervise its employees' disclosures to Congress is limited to privileged information. The discussion establishes only that the CRS interpretation that the 'right of disclosure' statutes prohibit Executive Branch supervision of employee disclosures unconstitutionally limits the ability of the President and his appointees to supervise and control the dissemination of privileged government information. However, the CRS position also unconstitutionally limits the President's ability to supervise and control the work of subordinate officers and employees of the Executive Branch more generally. See Constitutionality of Statute Requiring Executive Agency to Report Directly to Congress, 6 Op. O.L.C. 632, 633 (1982) (statutory 'requirement that subordinate officials within the Executive Branch submit reports directly to Congress, without any prior review by their superiors, would greatly impair the right of the President to exercise his constitutionally based right to control the Executive Branch'; provision would be unconstitutional if so construed); Authority of the Special Counsel of the Merit Systems Protection Board to Litigate and Submit Legislation to Congress, 8 Op. O.L.C. 30, 31 (1984) ('Congress may not grant [Special Counsel] the authority to submit legislative proposals directly to Congress without prior review and clearance by the President, or other appropriate authority, without raising serious separation of powers concerns').

This second, 'unitary Executive' position is based on the following rationale:

The [judicial] decisions and the long practical history concerning the right of the President to protect his control over the Executive Branch are based on the fundamental principle that the President's relationship with his subordinates must be free from certain types of interference from the coordinate branches of government in order to permit the President effectively to carry out his constitutionally assigned responsibilities. The executive power resides in the President, and he is obligated to 'take care that the laws are faithfully executed'. In order to fulfill those responsibilities, the President must be able to rely upon the faithful service of subordinate officials. To the extent that Congress or the courts interfere with the President's right to control or receive effective service from his subordinates within the Executive Branch, those other branches limit the ability of the President to perform his constitutional function.

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6 Op. O.L.C. at 638–39. Based on this rationale, we do not believe that the statutes relied upon by CRS could constitutionally be applied, as CRS would apply them, to the circumstance where a government official instructs a subordinate government employee not to provide an Administration’s cost estimates to Congress, whether or not the estimates are viewed as privileged.⁸⁰

On this issue, the Obama administration appears to be sending somewhat mixed signals. The recent executive order on scientific integrity is explicit that:

- (3) ... (b) Nothing in this memorandum shall be construed to impair or otherwise affect...:
- (ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

This seems to keep OMB’s existing controls over direct agency communications firmly in place. On the other hand, the ‘whistleblower’ provisions of President Obama’s directive on scientific integrity reflect one possible step toward openness—hopefully successful in [re]establishing an ethos, if not invariably successful in preventing suppression of data. And in a recent statement accompanying his signing of a piece of complex legislation, explaining his reservations about limited elements of the bill he was permitting to become law,⁸¹ President Obama wrote:

Executive Authority to Control Communications with the Congress. Sections 714(1) and 714(2) in Division D prohibit the use of appropriations to pay the salary of any Federal officer or employee who interferes with or prohibits certain communications between Federal employees and Members of Congress. I do not interpret this provision to detract from my authority to direct the heads of executive departments to supervise, control, and correct employees’ communications with the Congress in cases where such communications would be unlawful or would reveal information that is properly privileged or otherwise confidential.⁸²

Whether this is simply a reaffirmation that in some cases (nuclear weapons plans, for example) congressional demands for information must be denied in the interest of national security and the like, or rather a continuation of past practices of iron control over what information Congress sees remains to be seen. But note that in this statement President Obama, unlike his predecessors, limits

⁸⁰ www.usdoj.gov/olc/crsmemoresponses.htm, visited 19 March 2009. Shortly before leaving office, President Bush’s final Assistant Attorney-General in charge of the Office of Legal Counsel formally withdrew certain OLC opinions embracing ‘unitary Executive’ reasoning. In doing so, however, he mentioned only some that had become particularly controversial respecting presidential claims to emergency powers in the wake of September 11, 2001 attacks. NA Lewis, ‘Memos Reveal Scope of Power Bush Sought in Fighting Terror’, NY Times, 3 March 2009, at A1.

⁸¹ On the controversy over ‘signing statements’, hardly necessary to explore here, see R Cass and PL Strauss, ‘The Presidential Signing Statements Controversy’ (2007) 16 *William & Mary Bill of Rights Journal* 11.

⁸² Press Statement of 11 March 2009, www.whitehouse.gov/the_press_office/Statement-from-the-President-on-the-signing-of-HR-1105/, visited 13 March 2009.

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his reservation to 'cases where such communications would be unlawful or would reveal information that is properly privileged or otherwise confidential.' This seems a more limited, and readily accepted, claim than appears in the Bush 'unitary President' explanation.

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It is unreasonable to expect presidential-congressional struggles over executive privilege to cease.⁸³ As Congress itself recognised in including certain exemptions in the Freedom of Information Act, and as President Truman pungently remarked,⁸⁴ the President needs candid advice from his subordinates, and candour depends on confidentiality. Where the issue, however, is not advice, but data (viz, projections of the frequency with which orange-bellied parrots would be impinged on wind farm turbine blades at the projected Bald hills facility in Australia), the issues are quite different. The issue will be how widely and aggressively executive privilege is claimed.

One's impression is that the Obama administration understands these issues. But the proof will be in the pudding.

CONCLUSION

In concluding a paper presented to a conference on *global* administrative law, it may be appropriate to remind the reader that these are not simply American issues. One may be certain the issues of science-bending and the possible contributions to its control of transparency are present in *every* administrative law system—if not in connection with rule-making, then with contentious licensing issues.

The Internet and its ready searchability are global phenomena, so that questions about what information it should contain about governmental policy formation, made available to whom, and on what time schedule, are universal. Questions inviting scientific assessment frequently also involve uncertainties not completely resolvable by objective means, and/or kinds of risk to which the public is particularly sensitive. They may reflect matters of large public concern, on which the public, and politicians representing them, will understandably and acceptably wish to have a voice. The use of nuclear power, or of genetically modified organisms (GMOs) in the food chain, and the problems of global warming come readily to mind, and there are many like situations. One easily imagines situations like the more acceptable way of understanding the ozone controversy in the United States, in which generalist politicians are motivated by public interest considerations that may be missing from the particular law governing an agency's resolution of a matter. Understandable as it may be for them to inject these considerations into the decisional framework, that course

⁸³ See generally PM Shane, 'Negotiating for Knowledge: Administrative Responses to Congressional Demands for Information' (1992) 44 *Administrative Law Review* 197.

⁸⁴ See text accompanying  above.

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nonetheless presents troubling questions of legality. If the inadequacy of the existing legal framework is thus revealed, the proper response appears to be changing, not overriding, that framework. Beyond this lies the possibility that, less acceptably, individual politicians will act covertly in the interest of particular 'clients' to influence decision away from the point that an inquiry according to framework laws would determine.

To what extent is the data on which scientific assessments or political judgments may be based provided through the Internet, or in other ways exposed to public view? What are the contexts in which political interventions in an ostensibly objective (scientific) process may arise? To what extent are they transparent, so that the fact of them may be known? What if any controls are available to constrain their impact? These are questions of the broadest import. In the current day, given the high levels of concern about global warming, GMOs, and other matters, finding appropriate space both for the understandings science can bring and for the expression of democratic concerns that do not and need not regard all risks as commensurate, is challenging indeed.

Appendix A

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release March 9, 2009

March 9, 2009

MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND
AGENCIES

SUBJECT: Scientific Integrity

Science and the scientific process must inform and guide decisions of my Administration on a wide range of issues, including improvement of public health, protection of the environment, increased efficiency in the use of energy and other resources, mitigation of the threat of climate change, and protection of national security.

The public must be able to trust the science and scientific process informing public policy decisions. Political officials should not suppress or alter scientific or technological findings and conclusions. If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking. The selection of scientists and technology professionals for positions in the executive branch should be based on their scientific and technological knowledge, credentials, experience, and integrity.

By this memorandum, I assign to the Director of the Office of Science and Technology Policy (Director) the responsibility for ensuring the highest level of integrity in all aspects of the executive branch's involvement with scientific and technological processes. The Director shall confer, as appropriate, with the heads of executive departments and agencies, including the Office of Management and

Appendix A

Budget and offices and agencies within the Executive Office of the President (collectively, the 'agencies'), and recommend a plan to achieve that goal throughout the executive branch.

Specifically, I direct the following:

1. Within 120 days from the date of this memorandum, the Director shall develop recommendations for Presidential action designed to guarantee scientific integrity throughout the executive branch, based on the following principles:

- (a) The selection and retention of candidates for science and technology positions in the executive branch should be based on the candidate's knowledge, credentials, experience, and integrity;
- (b) Each agency should have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;
- (c) When scientific or technological information is considered in policy decisions, the information should be subject to well-established scientific processes, including peer review where appropriate, and each agency should appropriately and accurately reflect that information in complying with and applying relevant statutory standards;
- (d) Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions;
- (e) Each agency should have in place procedures to identify and address instances in which the scientific process or the integrity of scientific and technological information may be compromised; and
- (f) Each agency should adopt such additional procedures, including any appropriate whistleblower protections, as are necessary to ensure the integrity of scientific and technological information and processes on which the agency relies in its decisionmaking or otherwise uses or prepares.

2. Each agency shall make available any and all information deemed by the Director to be necessary to inform the Director in making recommendations to the President as requested by this memorandum. Each agency shall coordinate with the Director in the development of any interim procedures deemed necessary to ensure the integrity of scientific decisionmaking pending the Director's recommendations called for by this memorandum.

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3. (a) Executive departments and agencies shall carry out the provisions of this memorandum to the extent permitted by law and consistent with their statutory and regulatory authorities and their enforcement mechanisms.

(b) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) authority granted by law to an executive department, agency, or the head thereof; or

(ii) functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

4. The Director is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA

Appendix B

WORKING PRINCIPLES FOR RISK ANALYSIS FOR FOOD SAFETY FOR APPLICATION BY GOVERNMENTS

CAC/GL 62–2007

1. SCOPE

1. The Working Principles for Risk Analysis for Food Safety for Application by Governments are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health.

2. GENERAL ASPECTS

2. The overall objective of risk analysis applied to food safety is to ensure human health protection.

3. These principles apply equally to issues of national food control and food trade situations and should be applied consistently and in a non discriminatory manner.

4. To the extent possible, the application of risk analysis should be established as an integral part of a national food safety system.⁸⁵

5. Implementation of risk management decisions at the national level should be supported by an adequately functioning food control system/program.

6. Risk analysis should be:

- applied consistently;
- open, transparent and documented; and

Are foot-
notes
added by
author so
correct to
continue
numbering
as here, or
are they in
the original
document
so should
be 1,2 etc?

⁸⁵ It is recognised that national governments will use different approaches and time frames in the application of these principles taking into account national capacities and resources.

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- evaluated and reviewed as appropriate in the light of newly generated scientific data.

7. The risk analysis should follow a structured approach comprising the three distinct but closely linked components of risk analysis (risk assessment, risk management and risk communication) as defined by the Codex Alimentarius Commission,⁸⁶ each component being integral to the overall risk analysis.

8. The three components of risk analysis should be documented fully and systematically in a transparent manner. While respecting legitimate concerns to preserve confidentiality, documentation should be accessible to all interested parties.⁸⁷

9. Effective communication and consultation with all interested parties should be ensured throughout the risk analysis.

10. The three components of risk analysis should be applied within an overarching framework for management of food related risks to human health.

11. There should be a functional separation of risk assessment and risk management to the degree practicable, in order to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest. However, it is recognized that risk analysis is an iterative process, and interaction between risk managers and risk assessors is essential for practical application.

12. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

13. National governments should take into account relevant guidance and information obtained from risk analysis activities pertaining to human health protection conducted by Codex, FAO, WHO and other relevant international intergovernmental organizations, including OIE and IPPC.

⁸⁶ See Definitions of Risk Analysis Terms Related to Food Safety, Procedural Manual.

⁸⁷ For the purpose of the present document, the term 'interested parties' refers to 'risk assessors, risk managers, consumers, industry, the academic community and, as appropriate, other relevant parties and their representative organizations' (see definition of 'Risk Communication').

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14. With the support of international organizations where appropriate, national governments should design and/or apply appropriate training, information and capacity building programs that are aimed to achieve the effective application of risk analysis principles and techniques in their food control systems.

15. National governments should share information and experiences on risk analysis with relevant international organisations, other national governments (e.g. at the regional level through FAO/WHO Regional Coordinating Committees) to promote and facilitate a broader and, where appropriate, more consistent, application of risk analysis.

3. RISK ASSESSMENT POLICY

16. Determination of risk assessment policy should be included as a specific component of risk management.

17. Risk assessment policy should be established by risk managers in advance of risk assessment, in consultation with risk assessors and all other interested parties. This procedure aims at ensuring that the risk assessment is systematic, complete, unbiased and transparent.

18. The mandate given by risk managers to risk assessors should be as clear as possible.

19. Where necessary, risk managers should ask risk assessors to evaluate the potential changes in risk resulting from different risk management options.

4. RISK ASSESSMENT

20. Each risk assessment should be fit for its intended purpose.

21. The scope and purpose of the risk assessment being carried out should be clearly stated and in accordance with risk assessment policy. The output form and possible alternative outputs of the risk assessment should be defined.

22. Experts, involved in risk assessment including government officials and experts from outside government should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment. Information on the identities of these experts, their individual expertise and their professional experience should be publicly available, subject to national considerations. These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, including disclosure of conflicts of interest in connection with risk assessment.

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23. Risk assessment should incorporate the four steps of risk assessment, i.e., hazard identification, hazard characterization, exposure assessment and risk characterization.

24. Risk assessment should be based on scientific data most relevant to the national context. It should use available quantitative information to the greatest extent possible. Risk assessment may also take into account qualitative information.

25. Risk assessment should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects.

26. Constraints, uncertainties and assumptions having an impact on the risk assessment should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

27. Risk assessments should be based on realistic exposure scenarios, with consideration of different situations being defined by risk assessment policy. They should include consideration of susceptible and high-risk population groups. Acute, chronic (including long-term), cumulative and/or combined adverse health effects should be taken into account in carrying out risk assessment, where relevant.

28. The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded. The responsibility for resolving the impact of uncertainty on the risk management decision lies with the risk manager, not the risk assessors.

29. The conclusion of the risk assessment including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so that they can review the assessment.

5. RISK MANAGEMENT

30. National government decisions on risk management, including sanitary measures taken, should have as their primary objective the protection of the health of consumers. Unjustified differences in the measures selected to address similar risks in different situations should be avoided.

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31 Risk management should follow a structured approach including preliminary risk management activities,⁸⁸ evaluation of risk management options, implementation, monitoring and review of the decision taken.

32. The decisions should be based on risk assessment, and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles⁸⁹ as they relate to decisions at the national level. National Governments should base their sanitary measures on Codex standards and related texts, where available.

33. In achieving agreed outcomes, risk management should take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection, feasibility of enforcement and compliance, and the prevalence of specific adverse health effects.

34. Risk management should take into account the economic consequences and the feasibility of risk management options.

35. The risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties.

36. The outcome of the preliminary risk management activities and the risk assessment should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk.

37. Risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve. The option of not taking any action should also be considered.

38. Risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment

⁸⁸ For the purpose of these Principles, preliminary risk management activities are taken to include: identification of a food safety problem; establishment of a risk profile; ranking of the hazard for risk assessment and risk management priority; establishment of risk assessment policy for the conduct of the risk assessment; commissioning of the risk assessment; and consideration of the result of the risk assessment.

⁸⁹ See *Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to which other Factors are Taken in to Account*, Procedural Manual.

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of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, national governments should seek and take into consideration the potential impact of such measures on trade and select measures that are no more trade-restrictive than necessary.

39. Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions. The relevance, effectiveness, and impacts of risk management decisions and their implementation should be regularly monitored and the decisions and/or their implementation reviewed as necessary.

6. RISK COMMUNICATION

40. Risk communication should:

- i) promote awareness and understanding of the specific issues under consideration during the risk analysis;
- ii) promote consistency and transparency in formulating risk management options/recommendations;
- iii) provide a sound basis for understanding the risk management decisions proposed;
- iv) improve the overall effectiveness and efficiency of the risk analysis;
- v) strengthen the working relationships among participants;
- vi) foster public understanding of the process, so as to enhance trust and confidence in the safety of the food supply;
- vii) promote the appropriate involvement of all interested parties;
- viii) exchange information in relation to the concerns of interested parties about the risks associated with food; and
- ix) respect the legitimate concern to preserve confidentiality where applicable.

41. Risk analysis should include clear, interactive and documented communication, amongst risk assessors and risk managers and reciprocal communication with all interested parties in all aspects of the process.

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42. Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinion required for effective risk management is incorporated into the decision making process.

43. Risk communication involving interested parties should include a transparent explanation of the risk assessment policy and of the assessment of risk, including the uncertainty. The decisions taken and the procedures followed to reach them, including how the uncertainty was dealt with, should also be clearly explained. It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, and minority opinions that had been expressed in the course of the risk assessment (see para. 28).

Appendix C

DECLARATION OF INTERESTS FOR FAO EXPERTS

The assistance of distinguished authorities knowledgeable in a variety of scientific professions is essential to the work of the Food and Agriculture Organization of the United Nations (FAO). **It is expected that persons qualified to serve as an expert for FAO may have private interests related to the subject of their expertise. At the same time, it is imperative that situations be avoided in which such interests may unduly affect, or may be perceived to affect, an expert's impartiality or the outcome of work in which he/she was involved.**

To assure the highest integrity, and hence public confidence, in the activities of the Organization, FAO's regulations and policies require that all experts serving in an advisory role disclose any circumstances which could give rise to a potential conflict of interest (i.e., any interest which may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). Accordingly, in this Declaration of Interest (DOI) form, you are requested to disclose any financial, professional or other interest relevant to the subject of the work or meeting in which you will be involved and any interest that could be significantly affected by the outcome of the meeting or work. You are also asked to declare relevant interests of others who may, or may be perceived to, unduly influence your judgment, such as immediate family members, employers, close professional associates or any others with whom you have a substantial common personal, financial or professional interest. If you do not provide, where requested, the amount or value of the interest, it will be assumed to be significant.

Kindly complete this form and submit it to FAO Secretariat, well in advance of the meeting or work. You are also asked to inform the Secretariat of any change in this information that occurs before or during the course of the meeting or work. If FAO considers that a potential conflict of interest exists, one of several outcomes can occur, depending on the circumstances involved: (i) you may be invited to continue to participate in the meeting or work, provided that your interest would be publicly disclosed; (ii) you may be asked not to take part in the portion of the meeting, discussion or work related to your interest, or not participate in related decisions; or (iii) you may be asked not to take part in the meeting or work altogether. Non-completion of the DOI form would preclude further consideration of an expert's participation.

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Experts are requested to agree that any relevant conflicts may be **publicly disclosed** to other meeting participants and in the resulting report or other work product. The Secretariat will assume that you consent to such a disclosure, unless you check ‘no’ in the space provided on the last page of this form. In addition, the information disclosed by you **may later be made available** to persons outside of FAO if the objectivity of the work or meeting in which you are involved is questioned and the Director-General considers disclosure to be in the best interests of the Organization, although only after discussion with you.

Date and title of meeting or work, including description of subject-matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached):

Please answer each of the questions below. If the answer to any of the questions is ‘yes’, briefly describe the circumstances on the last page of the form.

The term ‘you’ refers to yourself, your employer and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your minor children). The term ‘commercial entity’ includes—aside from any commercial venture—an industry association, research institution or other organization whose funding is significantly derived from commercial concerns having an interest related to the subject of the meeting or work. The term ‘meeting’ also includes a series or cycle of meetings.

EMPLOYMENT AND CONSULTING

Within the past 3 years, have you worked for a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or negotiation for future work.

- 1a Employment Yes No
- 1b Consulting, including service as a technical or other advisor Yes No

RESEARCH SUPPORT

Within the past 3 years, have you or your department or research unit received support or funding from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or award for future research support.

- 2a Research support, including grants, collaborations, sponsorships, and other funding Yes No

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- 2b Non-monetary support valued at more than US\$1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.) Yes No

INVESTMENT INTERESTS

Do you have current investments (valued at more than US\$10 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified.

- 3a Stocks, bonds, stock options, other securities (e.g., short sales) Yes No
- 3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures) Yes No

INTELLECTUAL PROPERTY

Do you have any current intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?

- 4a Patents, trademarks, or copyrights (also include pending applications) Yes No
- 4b Know-how in a substance, technology or process Yes No

PUBLIC STATEMENTS AND POSITIONS (during the past 3 years) (questions relate to balanced composition of committee or group)

- 5a As part of a regulatory, legislative, judicial, or other governmental process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization? Yes No
- 5b Through your articles, editorials or speeches, could you be perceived as having taken a prominent or well-known position related to the subject of the meeting or work? Yes No
- 5c Do you hold an office or other position, paid or unpaid, where you may be expected to represent interests or defend a position related to the subject of the meeting or work? Yes No
- 5d Have you served as a principal investigator, as lead expert in an expert committee or scientific or advisory group, and/or a member of a steering committee, an advisory board or equivalent body in relation to the same product or subject matter? Yes No

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ADDITIONAL INFORMATION

- 6a If not already disclosed above, have you worked for the competitor of a product which is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor’s confidential proprietary information, or create for you a financial or commercial competitive advantage? Yes No

- 6b To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, financial or professional interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)? Yes No

- 6c Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence? Yes No

EXPLANATION OF ‘YES’ RESPONSES: If the answer to any of the above questions is ‘yes’, check above and briefly describe the circumstances on this page. If you do not provide, where requested, the amount or value of the interest, it will be assumed to be significant.

Nos. 1–4 Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) and basic descriptive details.	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, assumed significant)	Current interest (or year ceased)
Nos. 5–6: Describe the specific circumstances, parties involved, time frame and other relevant details				

CONSENT TO DISCLOSURE. The Secretariat will assume that you consent to the disclosure of any relevant conflicts to the other meeting participants and in the resulting report or work product, unless you check ‘no’ in the space provided here. If you check ‘no’, the Secretariat will not disclose the information without your prior approval, although this may result in your not being able to participate in the meeting or conference. **No:**

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DECLARATION. I hereby declare that the disclosed information is true and complete to the best of my knowledge. I undertake to inform the responsible staff of FAO of any change in this information or any new information that needs to be reported, which occurs before or during the meeting or work itself and through the period up to the publication of the final results.

Date: _____ Signature _____

Name

Institution

Address

Fax

Email

Telephone