

REGULATION OF AIR TOXICS IN WEST GERMANY
AND THE UNITED STATES: A COMPARATIVE
ANALYSIS OF ENVIRONMENTAL
STANDARD-SETTING

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Through an analysis of the regulatory proceedings for four case studies (including two air toxics-- cadmium, and dioxins in municipal waste incinerators), the authors found that the regulatory processes for promulgating control standards for hazardous air pollutant and other air emissions in the Federal Republic of Germany (FRG) and the United States of America (US) have some surprising similarities and significant differences. The differences appear to be based in both culture, and legal frameworks; therefore, the advantages of either system do not appear to be transferrable without significant changes. The authors further conclude that the transfer of information between the US and the FRG about pollution control technologies, health effects studies and other regulatory developments appear to have had, and no doubt will continue to have, the greatest impacts on the regulatory processes between the two countries. Regarding standard-setting for air toxics, the FRG has regulated more air toxics at the national level than the US. This paper briefly summarizes the basic air pollution control laws in the FRG, summarizes the FRG standard-setting process, and compares the standard-setting processes of the US and the FRG.

Introduction

The results of a comparative study of air pollution standard-setting, initiated in early 1985 at the Nuclear Research Center Juelich, near Cologne, Federal Republic of Germany (FRG), shows that some surprising similarities as well as significant differences exist in the regulatory approaches used in the FRG and the United States (US). This paper briefly summarizes the basic air pollution control laws in the FRG, summarizes the FRG standard-setting process, and compares the standard-setting processes of the US and the FRG.

The objectives of the study were to characterize the standard-setting processes in the US and the FRG for the purpose of determining if there were inherent advantages in either system, and to identify possible approaches that could be transferred. Four air quality standard-setting case studies, including two hazardous air pollutants, were used in this study.

Study Methodology

This comparison of the air quality standard setting procedures of the US and the FRG focused on four elements: first, understanding the procedures for setting air quality standards and the justification developed for them; second, identifying the role of risk assessment and scientific judgement; third, identifying the role of affected parties in the decisionmaking process; and, fourth, identifying the apparent advantages or disadvantages of either system and the potential for transferring regulatory procedures or approaches to the other country.

To accomplish these objectives, the authors selected four air quality case studies: lead, nitrogen dioxide, dioxins in municipal waste incinerators (MWI's), and cadmium. The two "air toxics", cadmium and dioxin, were chosen because cadmium was regulated in the FRG and not yet in the US, and dioxin was regulated in neither country but was receiving significant attention by regulators. Lead and nitrogen dioxide were chosen since each have been regulated for some time in both countries.

The basic data collection tools were two questionnaires administered to the major parties involved in each case study regulatory proceeding. These parties included agency/ministry officials, industrial trade association representatives, environmental groups, labor, and other individuals.

A detailed questionnaire sought to obtain information about: types of data and information used in the regulatory proceeding; timing, and mechanisms used by interest groups and involved parties to participate in the agency/ministerial process; regulatory options considered, and final rule promulgated; and, satisfaction of the interest groups with the process. The second questionnaire was administered to selected officials and interest group representatives. This questionnaire solicited opinions about the standard-setting process as a whole, and solicited suggestions for modifying the process.

The principal data gathering efforts occurred from March, 1985 to April, 1986.

The authors recognize that two other elements are important in studying the effectiveness of environmental regulation: that of implementation, and state-level standard-setting. These were not investigated due to time and budgetary limitations.

Principles of West German Environmental Law

Five basic principles of environmental management are embodied in West German law (1, 2). The first principle, Vorsorgeprinzip, specifies that pollution should be prevented. It enables the government to reduce environmental pollution even if the adverse effects and mechanisms are not yet fully understood by scientists. The administration is authorized to set emission standards to prevent potential harm to its citizens.

Second, the principle of "nach Stand der Technik", embodied in the Federal Emission Control Law, requires that the best available and demonstrated control technology is to be used. The control levels are determined by the individual states. (In West Germany, states are responsible for implementing most German environmental laws.)

Third, the Verursacherprinzip, specifies that the party responsible for pollution is responsible to pay for the clean-up. This also means that they are not responsible for clean-up costs for pollution that they do not cause.

Fourth, the Bestandschutzprinzip requires that future pollution control levels can not exceed existing levels. The fifth principle, the Kooperationsprinzip specifies that all parties who are potentially affected by a law must be consulted during the developmental process.

In Germany, new standards are not normally possible without an available, demonstrated, and affordable technology to achieve it. Standards are not usually technology-forcing, with one recent and notable exception. The recent requirements for large-fossil fired energy generating plants to meet stringent sulfur dioxide and nitrogen dioxide limitations has required the use of emerging selective catalytic reduction (SCR) technology from Japan, which may be technology-forcing. This example demonstrates that the development of new standards in the FRG is partially dependent upon information obtained from foreign sources. The authors also found that German governmental officials and non-governmental representatives were knowledgeable about scientific and technological developments in the US, as well as regulatory activities of the US Environmental Protection Agency.

In addition, a new technology may be introduced and adopted as the new "Stand der Technik" through a government program of economic incentives for developing new technologies. To assist in the development of new technologies, the West German government will finance up to 50 percent of the capital costs for an industry or company to install a new control technology through direct subsidies. If the new technology is

successful, the air pollution control levels achievable through installation of that technology are likely to become the new standard of technology (nach Stand der Technik), and can then become the new standards in the states and imposed on other companies.

The provision in West German environmental law for the use of the Stand der Technik also means that air pollution control requirements may change between formal revisions of air quality laws.

All of these principles are evident in the air quality laws and the standard-setting process described in this present paper.

West German Air Quality Laws

German air pollution control requirements are basically contained in only three laws: Federal Emission Control Law (Bundes Immissions-schutzgesetzes) of 1974, revised 1979; Technical Instructions on Air Quality Control (Technische Anleitung zur Reinhaltung der Luft), revised February 1986; and the Large Furnance Ordinance (die Grossfeuerungsanlage-Verordnung), revised 1984. These three laws, plus a specific law controlling lead in gasoline, are summarized below.

Federal Emission Control Act of 1974, revised 1979 and 1985 (Bundes Immissionsschutzgesetzes)

The Federal Emission Control Act of 1974, revised 1979, established the framework for West German air quality control. The law addresses air pollution control for all emission sources. It gave the Ministry of the Interior (since 1986, the Ministry of Environment) the responsibility for formulating and periodically revising standards.

The primary objective is to protect human health, but environmental (or welfare) protection is addressed, as well. The strategies for this protection are:

- (1) Ambient air quality standards. The objective is to not exceed defined air concentrations. The ambient standards theoretically provide guidelines for licensing of new facilities and for expansions of existing facilities. At present, only eight ambient air quality standards for public health protection have been promulgated.
- (2) Point source standards. Emitters must reduce their emissions to levels that are achievable with best available and affordable technology. So far, emission standards have been established for over 150 air pollutants, principally in the TA Luft (described below).

The law also requires the states (Laender) to issue regional ambient air quality improvement plans in areas with high pollutant concentrations. Most states have not yet issued these plans.

In late 1985, two revisions of the law were passed by the German Parliament. First, article 17 which previously had required standards for

existing plants to be economically justifiable, was changed to "economically reasonable." In the past, the courts interpreted "justifiable" to mean "financially manageable by the company." This new meaning implies that the standards should be met if the benefits are somehow proportional to the costs involved, not taking into account the financial status of the emitter. The second revision specified that emission control devices are to be regularly maintained so as to be as energy efficient as possible.

Large Furnance Ordinance of 1983, revised 1984 (Die Grossfeuerungsanlagen-Verordnung)

The air quality controls mandated in the Large Furnance Ordinance (die Grossfeuerungsanlagen-Verordnung, or GfO) would normally have been part of a revision to the Technical Instructions on Air Quality Control (TA Luft), since the TA Luft contains most of the air quality regulations and is periodically revised. However, political pressure on the Kohl government in 1983 to take action on air pollution in response to the acid rain problem (Sauer Regen, Waldsterben) resulted in the immediate passage of a separate measure addressing the large sources of sulfur dioxide, nitrogen oxides, and particulates.

This ordinance applies to all furnances/boilers over 50 megawatts thermal (MW_{th}). In 1983, these boilers contributed about 70 percent of total SO_2 , 33 percent of total NO_x , and 25 percent of total particulate emissions in West Germany. In addition to these pollutants, the GfO applied to carbon monoxide, and certain halogenated compounds.

By 1993, all old plants over 50 MW_{th} must meet new plant standards, or they must close. For example, the standards for large coal-fired power plants over 300 MW_{th} are listed on Table I. The requirements for old plants to meet new plant standards will result in a reduction in sulfur dioxide of 75 percent from 1982 to 1993. Nitrogen oxides will be reduced in 1993 by about 70 percent from 1982 levels.

Older plants are or will be installing retrofit controls. Of significant interest to US industry and regulators may be that West German regulators believe that NO_x controls, which have been demonstrated in Japan, are transferable to Germany. As of 1986, over 20 energy generating units were being fitted with selective catalytic reduction (SCR) units to control NO_x , or combined SO_2/NO_x control units (3).

Gasoline Lead Act of 1977

From 1977 to 1983, the law required refineries to have an average of no more than 0.25 grams per liter of lead in gasoline. Since 1983, the standard has been 0.15 grams per liter.

Unleaded gasoline was not available until 1985. The use of, and the manufacturing of, lead-free gasoline is not mandated, but is now needed for the increasing number of motor vehicles equipped with catalytic converters. Its use is also being encouraged with economic incentives.

Consumers pay less for unleaded gasoline at the pump, since taxes on unleaded gasoline are less than taxes on leaded gasoline. In addition, normal car taxes are reduced or waived for cars fitted with catalytic converters. The amount of tax reduction varies according to the size of engine.

In 1985, the Kohl government proposed a requirement that passenger motor vehicles available for purchase in West Germany be equipped with catalytic converters. Such regulations would affect trade within the European Community. Therefore, Germany was obligated to consult with the other EC members. It became clear during negotiations with the other EC countries that France and Italy would likely bring Germany's law to the European Court in The Hague. Under these circumstances, the Kohl government withdrew the proposal.

Technical Instructions on Air Quality Control,
as amended in February, 1986
(Technische Anleitung zur Reinhaltung der Luft)

The Technical Instructions on Air Quality Controls (TA Luft) are promulgated by the Environment Ministry, with approval of the Bundesrat. Except for the Federal Emission Control Act, and GfO, and the Federal Gasoline Law, all national air pollution control requirements are embodied in the TA Luft.

The first version of the TA Luft was issued in 1964, and was revised in 1974. Another revision was initiated in 1985 by the Interior Ministry (which then had the environmental responsibility for the federal government) and promulgated in February 1986.

Major provisions. In general, the TA Luft sets ambient, point source, industrial source, and performance standards. It does not regulate large furnances, since those are regulated under the GfO. TA Luft does regulate boilers with a capacity of less than 50 MW_{th} for solid-fuel fired and oil boilers, and for gas-fired boilers less than 100 MW_{th}.

Old plants must meet new plant requirements under TA Luft. If a plant exceeds emission limitations by three times, it must be in compliance by March 1, 1989. If it exceeds the standards by one and one-half times, then a March 1, 1991 deadline is imposed. Plants with exceedances of less than one and one-half times have a deadline of March 1, 1994.

Ambient "primary" standards are set for dust, lead, cadmium, chlorine, hydrochloric acid, carbon monoxide, sulfur dioxide, and nitrogen oxides (see Table II). Depositional secondary ambient standards were set for dust, lead, cadmium, and thallium, and an ambient standard was also set for fluorine (see Table III).

Point source air pollutants are classified into two groups: carcinogens and others. Carcinogens are further divided into three classes; Class I- most carcinogenic, Class II, and Class III- least

carcinogenic. The carcinogens and the emission limitations are listed on Table IV.

Other air pollutants are also divided into three classes varying from Class I- most toxic, to Class III- toxic. These are divided into organics, inorganic solids, gaseous and vaporous inorganics. Tables V to VII contain the standards for these regulated chemicals.

This new version of TA Luft contains other provisions for the overall national West German air quality control program. These provisions include: measuring and monitoring procedures; stack height limitations; and allowances for "bubbles" over complex sources. The bubble concept was not in previous versions of the TA Luft.

Federal Environmental Administration in West Germany and Major Parties Involved in Standard-Setting

Federal Administration

The Ministry for Environment, Nature Conservation, and Reactor Safety (Bundesministerium fuer Umwelt, Naturschutz, und Reaktorsicherheit) is responsible for coordinating national environmental matters, including the promulgation of national air quality regulations. This ministry was created by Chancellor Helmut Kohl in 1986. It was created from the parts of the Interior Ministry, the Federal Environment Agency, the Agriculture Ministry, and the Federal Health Agency. Prior to November 1986, the Interior Ministry was responsible for coordinating environmental matters. The Environment Minister is appointed by, and reports to, the Chancellor.

While the Environment Ministry has the authority to promulgate national environmental standards, the states have the responsibility for implementation and enforcement of practically all environmental regulations. The principal exceptions are federal public works construction and nuclear safety.

The Environment Ministry in Bonn is responsible for establishing air quality regulations. Research support comes from the Federal Environment Agency (a subordinate agency to the Environment Minister), and Federal Health Agency (a subordinate agency to the Minister of Health), both located in Berlin.

Major Parties Involved in Standard-Setting

In addition to the Environment Ministry, three other parties play a significant role in the West German standard setting process. These parties are the Association of German Engineers (Verband der Deutsche Ingenieur, or VDI), the German Research Society (Deutsche Forschung Gemeinschaft, or DFG), and the states' Environment Ministers' Conference (Umweltministeriumskonferenz, or UMK). None of these are governmental institutions, but each plays a major role in environmental standard-setting in the FRG. For example, the VDI and a commission of the DFG are directed by law to make recommendations on new and revised

environmental regulations. For this work, these organizations are compensated with public funds.

The VDI, the principal professional association of German engineers, has standing and ad hoc "expert" committees. These committees identify emerging environmental problems, develop recommendations for new standards, and advise government and private decisionmakers on other matters. The output of the VDI's environmental issues-oriented committees are routinely forwarded to the Environment Ministry.

The DFG, somewhat akin in the US National Academy of Sciences, also has standing and ad hoc committees which study environmental management issues and develop recommendations for the government. The DFG, for example, has a standing committee on occupational standards (called the Maximalarbeitskonzentration Werte Kommission, or MAK). The members of the MAK are appointed by the Health Minister (Gesundheitsministerium), but the committee is administered by the DFG.

The MAK committee also makes determinations about the carcinogenicity of chemicals. For substances judged to be carcinogenic, the MAK committee classifies carcinogenic material into one of three classes. Each class has prescribed standards for occupational exposure and point source emissions. The results of these determinations are important, not only for the resulting standards that may become established, but also the decisions on carcinogenicity determine which agency has purview over the substance. If a substance is judged to be carcinogenic, the Federal Health Agency normally has jurisdiction; "non-carcinogenic" substances are the responsibility of the Federal Environment Agency and the Environment Minister.

The Umweltministeriumskonferenz (UMK) is composed of representatives of state-level environment ministries. The UMK normally reviews proposed regulations during or after initial drafting within the Ministry. The UMK also has committees (e.g. on air, water) where problems and proposed solutions are initially discussed. Within these committees, too, consensus recommendations are forged, prior to formal action by the states' environment ministers. Recommendations are then forwarded to the Environment Ministry.

Normally, a proposal that is endorsed by the UMK is adopted by and promulgated by the Environment Ministry, and later signed into law. The UMK's approval is critical because all rules must also be endorsed by the Bundesrat, a house of the German Parliament. The Bundesrat is composed of appointed members from each state government.

The generation of proposals and the review of issues and proposed regulations is not restricted, however, to these parties noted thusfar. The Environment Ministry may also form ad hoc committees, or working groups, to investigate specific issues.

The ministry is responsible under German law, as noted in the discussion of the five principles, to consult with affected parties during the development of regulations. During the development of regulations, the ministry may have substantial contact with outside interest groups

(e.g. individual companies, or trade associations) who may be affected by the proposed regulations. This contact can include private, "closed door" negotiation sessions. By FRG standards, this is fair and normal practice. The ministry, however, has the discretion to identify affected parties and to invite them to participate in public review and comment sessions.

The emphasis of the German system is on consultation with affected parties, and a balancing of interests. Civil servants act as mediators of affected parties. They are responsible for maximizing the public welfare by: acquiring information from subordinate agencies, scientists and technical experts, and affected parties; listening to viewpoints of affected parties; and, attempting to then determine appropriate government action.

West German Standard-Setting Process

On the basis of interviews with representatives of the Interior Ministry (now the Environment Ministry), industry trade associations, professional societies, German policy and legal experts, and other interest groups, the process appears to function in ten basic steps. These steps are:

1. Identification of problem or need for regulatory activity (not a formal decision making step). In this step, parties within the Environment Ministry and government, as well as non-governmental parties, identify an environmental problem, a change in best available pollution control technology, political circumstance, or other situation for which a new regulatory initiative appears needed. These suggestions come to the attention of the Environment Ministry through formal and informal communications. For example, the Society of German Engineers (VDI), or the German Research Society (DFG) could communicate some concerns and/or proposal ideas to contacts within the Ministry.
2. Development of proposed regulatory action within the Federal Environment Agency and Environment Ministry. The Federal Environment Agency (UBA) is an agency within the Environment Ministry. It serves as the environmental and health evaluation branch of the Environment Ministry. Proposals for regulations may originate in UBA and are then circulated to the Environment Ministry.
 - 2.a. Federal Environment Agency. Three principal groups within the Federal Environment Agency (UBA) are involved in the standard setting process, and a step-wise evaluation and proposal development process is followed.

Evaluations of potential health risks results in judgements about no-adverse effects levels (NOELs) of air pollutants. Subsequent to, or during these health evaluations, engineering evaluations commence wherein solutions to control emissions to the NOEL level (or as close to that level as possible) on the basis of available technology are identified.

Subsequently, a proposal is formulated largely based on the engineering determination of best available and affordable technology that will achieve reductions to match the NOEL. This proposal is circulated to UBA's legal staff wherein a review of court cases and laws is made. After any modifications are made, the proposal is returned to the engineering staff for final review and modifications. Scientists and other knowledgeable people (including those associated with potentially affected parties) may be consulted during this process, too. Upon finalization, UBA submits a proposal to the Environment Ministry.

- 2.b. Environment Ministry. The UBA proposal may be considered by the Ministry staff, along with proposals from the VDI or others. Reflecting the civil servants' mission of consultation and balancing of interests, outside groups (again, scientists and/or potentially affected parties) may be asked to comment on draft ideas during the Ministry's review of the proposals. The Ministry will then formulate a definite proposal.
3. Environment Ministry circulates the proposal to, and has discussions with, affected and interested parties (including other ministries or agencies). Discussions can include "closed door" negotiation sessions with potentially affected parties. Industrial groups are usually the parties involved in these negotiations, while "public interest" groups have not usually been a part of the process. "Experts" from other sources (e.g. from national research centers, universities) are often included in ministerial discussions.

If the initiative for federal action has not originated with the states, or the states' Environment Ministers Group (the UMK), these parties are normally consulted at this early stage. Such consultation is important since representatives of each state, who sit in the Bundesrat (one of two houses of the West German parliament), must approve regulations before they can become law.

4. Environment Ministry revises the proposal and circulates it to affected and interested parties. The Ministry identifies the parties which should be consulted and invites them to discuss their comments on the proposal with the Ministerial staff. This consultation step is required in the Federal Emissions Control Act.

Formerly, environmental and public interest organizations have been viewed as "outside" of the regulatory process, and have not been consulted during this step. They were regarded as not having significant information and expertise to offer to the Ministry. In more recent times, these outside groups have been approached but they did not participate in discussions. They have sent written comments to the Ministry.

5. Public meetings organized by the Environment Ministry. At the discretion of the Ministry, public meetings may be held wherein the Ministry invites experts and potentially affected parties to attend and discuss their comments on the issues and proposals.

6. After revisions, proposed regulations are circulated to other ministries for review and comment. After discussions with potentially affected groups, the Environment Ministry will revise its proposal and reissue it. The ministers for Health, Agriculture, Economics, and Research & Technology, review the proposed regulations. All of these ministers may receive comments about proposed regulations from outside groups. For example, industry may forward its concerns to the Economics Minister about costs associated with implementing a proposed regulation, while, scientists' concerns may be sent to the Research and Technology Ministry. These and other outside groups do so hoping that the minister will voice concerns to the Environment Minister and offer suggestions for revisions.

By this time, the states' environment ministries will have agreed on a proposal, in consultation with the government.

7. Review of proposed regulations by the Cabinet, and vote of support. If a proposed regulation affects areas under the purview of other ministries, the proposed regulation must be co-signed by that affected ministry. After appropriate deliberations, the Cabinet must make a formal decision to issue the proposed regulations.
8. Proposed regulation is published in the official Federal noticing publication, the Bundesgesetzblatt, which is similar to the US Federal Register. In the case of environmental regulations, the Environment Minister would place the notice, after Cabinet approval.
9. Vote by the Bundesrat. Approval by this house of the West German parliament is necessary before regulations are effective. Normally, this process is without great acrimony as state and regional issues will have been addressed earlier in the standard-setting process. Recently, this step has been more important as interests urging the adoption of stronger environmental laws have been more effective in raising these issues through the Bundesrat.
10. Signature by Federal President. Assuming that the measure has been approved by the Bundesrat, the regulation goes to the Federal President for signature. While this step is required by West German law, the President's signature is essentially automatic.
11. Court Challenges. Under German constitutional and administrative law, a regulation can be challenged on only two grounds. A request can be filed with the Constitutional Court stating that the new law violates the Federal Constitution, or the Administrative Law Court can be petitioned that the procedure used in developing and approving the new regulation was improper.

The US Standard-Setting Process

Federal Government and Major Parties Involved in Standard-Setting Process

In the US, the principal federal entity promulgating regulations affecting air, water, and solid and hazardous waste is the US

Environmental Protection Agency, headed by an Administrator who is appointed by, and reports to, the President of the United States. While other agencies promulgate, implement, and enforce, regulations affecting environmental quality (such as the Department of the Interior), EPA has the prime responsibility for air quality standard-setting.

EPA is charged with implementing the Clean Air Act (CAA). Under this act, EPA is responsible for setting standards for national ambient air quality (NAAQS), new source performance standards (NSPS), hazardous air pollutant, or air toxics (NESHAP), and mobile source emission controls (including lead in gasoline).

In the US, the standard-setting process is open and accessible to all parties. In addition to EPA, major industry trade associations, individual companies, environmental and public interest organizations, state and local governments, labor, and other groups are often closely involved in EPA's process. This involvement includes: reviewing proposed regulations; discussions with agency staff before promulgation; attending meetings of the Clean Air Scientific Advisory Committee (CASAC) and other committees and subcommittees of EPA's Science Advisory Board; making presentations at SAB meetings; and, providing written comments to the agency.

The steps in the regulatory processes are well known to the interested parties, and the status of individual standard-setting proceedings can be easily tracked. In contrast to the West German system wherein most of the air quality regulations are contained in one document, which is only periodically revised, the US air quality regulations are numerous. At any point in time, formal standard setting proceedings are ongoing for NAAQS, NSPS, and NESHAP proceedings, as well as for mobile source controls, and other air pollution control programs.

Under German law, a new chemical could be regulated within the TA Luft, between the formal, ten-year revisions if the states' environment ministers agree to the action. If the ministers agree, then the regulations become states' law.

The US process leads to a standard with a substantial data base that justifies the standard, and this justification is published. Such justification is a requirement of the US system of government (4).

US Standard-Setting Process

The process for setting air quality standards differs somewhat among the three major, non-mobile source standard-setting proceedings for NAAQS, NSPS, and NESHAPs. The differences among the processes are: the specific scientific committee of the Science Advisory Board or other EPA advisory committees involved, and kinds of data and information used during the regulatory development process. The differences in approaches between the US and the FRG are primarily that of the extent of public review throughout the entire process, and the specified structure to the development process.

Since most readers are already familiar with the US process, the following is a brief, generalized description of one air quality standard-setting process, that being for NAAQS (5).

1. Agency staff and/or contractors prepare a criteria document. The criteria document, prepared by EPA's Environmental Criteria and Assessment Office, summarizes the scientific health studies relevant to the consideration of appropriate acceptable standards for the criteria pollutant subject to the proceeding (e.g. nitrogen oxides).
2. Criteria document chapters reviewed in draft form in open, public workshops with agency staff, interest groups, etc. and a member of the Clean Air Scientific Advisory Committee (CASAC).
3. Criteria document chapters are revised by agency staff and/or contractors, where appropriate.
4. Criteria document is reviewed by CASAC in an open, public meeting. Time is allotted on the agendas for presentations by interested parties.
5. "Staff paper" is prepared, summarizing the scientific studies, identifying key issues, and making recommendations for regulatory action. Paper is prepared during CASAC's review of the criteria document by EPA's Office of Air Quality Planning and Standards.
6. Staff paper and criteria document are reviewed and approved in an open, public meeting by CASAC.
7. Draft rules are developed by EPA staff, after criteria document and staff paper are approved by CASAC.
8. Draft rules are internally reviewed at EPA, including the "Red Border" review by all assistant administrators.
9. During EPA internal review, the President's Office of Management and Budget (OMB) reviews the draft rule and a preliminary Regulatory Impact Analysis (RIA) is prepared in accordance with Executive Order 12291 to insure that "(b) Regulatory action shall not be taken unless the potential benefits to society for the regulation outweigh the potential costs to society" (6).
10. After approval by OMB and the assistant administrators' "red border" review, the Administrator may formally propose the regulation by publishing it in the Federal Register.
11. Public comments are solicited. Normally, the comment period is 45 - 60 days, though extensions may be granted.
12. EPA staff and/or contractors respond to comments, and revise the proposed regulation.
13. Revised rule undergoes internal EPA review (including "red border" review), as well as OMB review.

14. Once approved by OMB, the Administrator promulgates the final rule by publishing it in the Federal Register.
15. Involved parties have 60 days to file a petition with the Administrator asking him/her to reconsider the final rule. Court challenge is also possible.

These steps are not exactly applicable to the processes for promulgating standards under the NSPS or NESHAP programs, but the level of public review, the openness of the process, and the basic approach are similar. For example, the NAPCTAC (National Air Pollutant Control Technology Advisory Committee) is involved early in the process of establishing NSPS. In NESHAP, the Environmental Health Subcommittee of the Science Advisory Board plays a major role.

In general, US interview respondents expressed having less knowledge about scientific study results, technological developments, and regulatory activities in West Germany and Europe, than their West German counterparts had about US activities. The authors postulate that this is in part due to less foreign language knowledge in the US.

Comparison of Air Quality Standards Reviewed During Study

This section provides brief commentary on both ambient and hazardous air pollutant standard-setting, with emphasis on air toxics.

Comparisons of ambient primary and secondary standards are contained on Tables II and III. The primary ambient standards in the two countries vary. In some cases, they are comparable, though the averaging times are somewhat different. The greater differences in ambient standards comes in the secondary standards, where the FRG depends on depositional standards except for fluorine.

For hazardous air pollutants, the FRG has more national point source emission standards than in the US. At present, the US regulates eight air toxics, and has issued notices of intent to list under Section 112 of the Clean Air Act for ten substances. Over 30 other substances are currently being studied by EPA. In addition to national regulations, states in the US are quite active in air toxics control programs, with 35 states having ambient guidelines, seven states with ambient standards, and 26 states with control technology programs. Air toxics are also addressed nationally through means other than through Section 112; for example, through the Toxic Substances Control Act, and the Resource Conservation and Control Act.

For the comparative standard-setting project, the authors used dioxins in municipal waste incinerators (MWI's) and cadmium proceedings in both countries, for two out of a total of four case studies to define the standard-setting process. North American attendees and readers may find the German experience of particular interest.

For dioxins, neither country currently has national standards limiting emissions from MWI's. The potential health risks posed by dioxin emissions from these facilities were identified in the early 80's in both countries. In Germany, some sampling results within the country and from Sweden triggered interest. In 1984, the Interior Ministry formed a Dioxins Working Group composed of representatives from the states, the research community, federal ministerial staff, and industry. They were charged with the responsibility of assessing the potential public health risks stemming from possible dioxin emissions from MWI's.

The working group concluded later in 1984 that national standards were not needed, and they made recommendations about appropriate operational performance guidelines for MWIs that would further reduce any emissions of dioxins. For example, burn temperatures should remain between 800-1200° C, depending upon the composition of the feedstock. Carbon monoxide should be limited to 100-1000 mg per cubic meter, particulates limited to 50-100 mg per cubic meter, and total organics should be limited to 20 mg per cubic meter. Other suggestions were included in their final report, including the conclusion that continuous emission monitoring was too expensive.

While the Ministry has been inclined to issue performance standards for MWI's to limit dioxin emissions, many of the states want the Ministry to issue emission standards for dioxins from MWIs. This issue has not been resolved to-date.

In the US, the Environmental Protection Agency has been studying the issue, sponsoring monitoring studies, and expects to issue a comprehensive report on emissions from MWI's for Congress in the spring of 1987. State and local governmental attention to this issue has been significant, as numerous proposals for MWI's have been the catalyst for local concerns about dioxin emissions. Those having interest in state and local activities may wish to contact the State and Territorial Air Pollution Administrators Association (STAPPA) or EPA's Office of Air Quality Planning and Standards (OAQPS) for more information.

Cadmium emissions have been regulated in the West German TA Luft since 1974. It is not classified as a carcinogen, but is Class I toxic. Point source emissions are limited to 0.2 mg per cubic meter. Ambient levels are limited to 0.04 micrograms per cubic meter (primary) and 5.0 micrograms per square meter per day (secondary, depositional). During the latest TA Luft revision, some objections were raised by industry to the classification of cadmium being in the Class I group with the attached emission limitation, and to the depositional limitation of 5 micrograms. Two public hearings were held to listen to the views of industry and experts. The issues centered on industries' ability to comply with the emission requirements, and the amount of cadmium actually accumulating through deposition. In the final revision, the stricter limitations prevailed.

While EPA has issued a notice of intent to list cadmium as a hazardous air pollutant, it is not now directly regulated under the Clean Air Act's Section 112 provisions. The agency continues its analysis.

Attendees and readers who may wish to make contacts in West Germany about these issues should contact the authors.

Comparison of Standard-Setting Processes

Air quality standard-setting in both countries relies upon ambient and point source emission standards. While this study did not attempt to collect data on implementation effectiveness, the authors were told that ambient standards have not been vigorously enforced by the states in the FRG. Ambient standard-setting, therefore, may be more significant in the US.

The processes for setting environmental standards in the US and the FRG appear to be quite different, but are in fact only different in degree and style. Citizens of the FRG, however, seem to have different attitudes toward the role of government, civil servants, and the role of science. The opinions of scientists and experts carries much weight in the FRG (7). In addition, citizens have traditionally trusted the civil servant to truly represent their interests and to appropriately balance all interests, though recently environmentalists appear to be less accepting of this traditional trust relationship.

The US system is open and adversarial, where documentation and justification are critical. The FRG system involves more "closed door" negotiations, and dependence of "expert committees" which are not formal governmental entities. Specific interest groups are involved, but the method of involvement and the invitation for involvement are largely done at the discretion of the government. There does appear, however, to be increasing pressure to "open up" the process.

Explicit health risk assessments and formal cost/benefit analyses appear to have less of a role in the FRG rulemaking process than in the US. However, the authors were told that industry, and the environmental groups, in the FRG would like to see such assessments introduced into the public rulemaking process so that their issues can be better aired. In the US, health assessments are subject to rigorous public scientific peer review, while these assessments appear to be more judgemental and occur early in the standard-setting process in the FRG.

The FRG approach appears to be more accommodating to time pressures, and the government can respond relatively quickly to pressing issues. In the US, due process dictates an orderly, deliberate, and lengthy decisionmaking process.

Consideration of economics and available control technologies seems to be important in both the US and FRG standard-setting. In the US, however, only health effects can be considered in the establishment of National Ambient Air Quality Standards.

The outcomes, then, of the standard setting processes in the US seem to be determined by scientific studies and environmental evidence which must be supportable and documented. When legal, economics and technological availability and effectiveness appear to play some role.

In West Germany, the final decisions of standards lies in technical feasibility of achieving reductions at reasonable costs, and the levels are agreed upon through negotiations, largely without "public involvement" as is practiced in the US, and with little resulting written, public justification.

A shared characteristic of the two systems is that none of the involved, interested parties are normally satisfied with the end result, at least not publically. However, the environmental groups in both countries seem less satisfied with the processes than does industry.

The major points of conflict in the US standard-setting centered on: a) disputes over whether the marginal increases in health benefits were worth the marginal increased costs of pollution control; b) the applicability of animal studies to human health; c) quality of the data in studies used considering appropriate human health exposures. In the FRG, the major conflicts in the regulatory process also seemed to be: a) affordability of control technologies; and b) quality and applicability of data to human health exposures experienced in reality.

The transfer of information between the US and the FRG, as well as between other Western nations, about health risks, technological developments and regulatory activities appears to have a significant impact on the standard-setting activities of each country. For example, the construction of SCR units for controlling NO_x emissions at fossil-fuel fired power plants was a major factor leading to the West German adoption of strict NO_x retrofit requirements for existing power generating stations. Air pollution scientists in both countries are aware of developments regarding dioxins in MWI's.

The authors were not able to clearly identify any element of either country's approach that appeared to offer distinctive advantages to the other country's standard-setting process. It appears that each process reflects the constitutional requirements and cultural and social traditions such that neither country's standard-setting approach or process could work in the other. However, the authors note that certain aspects of the respective approaches are being tried, or at least elements are attractive. For example, the US EPA has successfully used a regulatory negotiation process for a number of standard-setting efforts. In the FRG, some interest groups recommended incorporating more explicit considerations of analytical health risk assessments and cost/benefit analyses.

Recommendations for Improvements in the Standard-Setting Process

In addition to obtaining background information about each of the case study standard-setting processes, respondents were asked to provide ideas for improving the existing regulatory processes.

In the FRG, the suggestions included:

- the process should be more open to interested parties;

- the rationale for decisions made throughout the regulatory process should be more explicit and publicly available;
- the process should be more flexible, with the Ministry having greater discretion;
- economic incentives should be used more to encourage the development of pollution control technologies;
- the enforcement of ambient standards should be strengthened;
- use of health risk assessments should be incorporated into the Environment Ministry's regulatory development process;
- non-governmental groups (industry, environmental and public interest) should be involved earlier in the process; and,
- the use of cost-benefit analysis should be made a part of the formal standard-setting process.

In the US, the comments have included:

- federal funding should be provided to public interest groups, so that they can adequately and effectively participate in the process;
- the open, adversarial process is essentially good and will remain with us. The length of the process does reduce the chances for making hasty and misinformed decisions;
- the process probably can be shortened in some ways, for example, many studies could be incorporated into the NAAQS criteria document by reference rather than spending time and resources to include these studies in the criteria document for each NAAQS revision. The time requirements would be less, and the system, therefore, can be more responsive to changes in scientific information;
- regulatory negotiation, or "reg neg" seems to be perceived as being useful, with some limitations;
- Some respondents indicated that OMB should be excluded from the rulemaking process, particularly in NAAQS rulemaking since ambient standards are supposed to be only health-based; for others, OMB review appeared to be welcomed;
- standard-setting should consider whether the marginal benefits of a proposed rule are really worth the marginal costs; and,
- While theoretically appealing, industrial "self-regulation" had limited applications according to respondents. To some respondents within industries regulated by public utility or public service commissions, implementing some forms of self-regulation would be difficult without PSC/PUC approval.

Others questioned whether industry could be trusted to self regulate.

While numerous respondents indicated an interest in having the process shortened, EPA indicated that up to 80 percent of its final regulations are challenged (8). Given the due process requirements, court challenges, and justification requirements, developing mechanisms for shortening the process will be itself a challenge. EPA's Regulatory Negotiation Project, however, has demonstrated that alternative strategies may be attractive for reducing time requirements and improving satisfaction with the end results.

Conclusions

Given the differences in constitutional and administrative law, as well as in culture, it is apparent that the procedures for setting standards are not directly transferrable, even if some aspects of one system appear to be more attractive. However, the authors have not seen any specific aspect of either system that would appear to greatly benefit the other. The greatest transnational impacts appear to be that of information transfer of air pollution control technologies, and basic scientific information.

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Other individuals contributing to this project included: Hans Peter Peters, Nuclear Research Centre Juelich, FRG; Michael Lingnau, Bonn, FRG; Sidney Shapiro, University of Kansas; Robert Wenger and Cheryl Morton, ENVIRON Corporation; Ekhard Bergmann, Karl-Heinrich Hansmeyer and Thomas Hobein, University of Cologne, FRG; and, Horst Mierheim, Siegfried Kalmbach, Horst Neidhard, Bernd Schaerer, and Wolfram Wycisk, Berlin, FRG.

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NOTE-- Much of the information presented in this paper was based upon personal interviews conducted by the principal investigators between March 1985 to April 1986, with federal and state agency and ministerial officials, industrial trade association representatives, environmental organization representatives, labor union staff, and other individuals in universities, and other organizations in the United States and West Germany. Respondents normally requested that statements be held in confidence. A list of respondents may be obtained from the principal investigators.

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Table I. Emission standards for large coal-fired power plants
in Federal Republic of Germany (over 300 MW_{th}, or 100 MW_{e1})

	(in mg/m ³)		(in mg/m ³)
HCl	100.0	HF	15.0
DUST	50.0	NOx	200.0
SO ₂	400.0 ^a	HEAVY METALS	0.5
CO	250.0	(As, Pb, Cd, Cr, Co, Ni)	

Note:

^a In addition, maximum of 15 % of SO₂ in coal allowed in flue gas

Source: Heber, Bundesministerium fuer Umwelt, 1986

Table II. Primary ambient air quality standards
in the Federal Republic of Germany and the United States.

	FRG		US		unit
	I W 1 ^a	I W 2 ^b	LONG	SHORT	
DUST	0.15	0.30	0.075 ^c	0.26 ^d	mg/m ³
Pb	2.00	---	1.50 ^e	---	ug/m ³
Cd	0.04	---	---	---	ug/m ³
Cl	0.10	0.30	---	---	mg/m ³
HCl	0.10	0.20	---	---	mg/m ³
CO	10.00	30.00	10.00 ^f	40.00 ^g	mg/m ³
SO ₂	0.14	0.40	0.08 ^a	0.365 ^h	mg/m ³
NO _x	0.08	0.20	0.10 ^a	---	mg/m ³
OZONE	---	---	0.235 ⁱ	---	mg/m ³

Notes:

a arithmetic annual mean

b 98% value of cumulative frequency distribution

c geometric annual mean

d maximum 24 hour concentration, not to be exceeded more than 1 per year

e maximum arithmetic mean averaged over a calendar quarter

f 8 hour average concentration not to be exceeded more than 1 per year

g 1 hour average concentration, not to be exceeded more than 1 per year

h max. 24 hr concentration not to be exceeded more than 1 per year

i max. hourly average; not to be exceeded more than 1 day per calendar year

Source: TA Luft, 1986; 40 CFR 50, July 1, 1986.

Table III. Secondary ambient air quality standards
in the Federal Republic of Germany and the United States.

	FRG (deposition, except F)			US		unit
	I W 1 ^a	I W 2 ^b	unit	LONG	SHORT	
DUST	0.35	0.65	g/m ² /d	0.06 ^c	0.05 ^d	mg/m ³
Pb	0.25	---	mg/m ² /d	1.50 ^e	---	ug/m ³
Cd	5.00	---	ug/m ² /d	---	---	ug/m ³
Tl	10.00	0.30	ug/m ² /d	---	---	mg/m ³
F	1.00	3.00	ug/m ³	---	---	mg/m ³
SO ₂	---	---	---	1.300 ^f	---	mg/m ³
NO _x	---	---	---	0.010 ^g	---	mg/m ³
O ₃	---	---	---	0.235 ^h	---	mg/m ³

Notes:

^a arithmetic annual mean

^b 98% value of cumulative frequency distribution

^c geometric annual mean

^d maximum 24 hour concentration not to be exceeded more than 1 per year

^e maximum arithmetic mean averaged over a calendar quarter

^f maximum 3 hour concentration not to be exceeded more than 1 per year

^g annual arithmetic annual concentration

^h max. hourly average; not to be exceeded more than 1 day per calendar year

Source: TA Luft, 1985; 40 CFR 50, July 1, 1986.

Table IV. Emission standards for carcinogenic air pollutants in the Federal Republic of Germany.

Carcinogen Class and Pollutants	Emission Standard
CLASS Ia Asbestos, as fine dust Benzo(a)pyrene Beryllium Dibenz(a,h)anthracene 2-Naphthylamine	0.1 mg/m ³
CLASS Ib Arsenic (respirable form) Chromium (respirable form) Cobalt (respirable form) 3,3-Dichlorobenzidine Dimethyl sulfate Ethylenimine Nickel (respirable form)	1.0 mg/m ³
CLASS IIc Acrylonitrile Benzene 1,3-Butadiene 1-Chloro-2,3-epoxypropane (epichlorohydrin) 1,2-Dibromomethane 1,2-Epoxypropane Ethylene oxide Hydrazine Vinyl chloride	5.0 mg/m ³

Notes:

- a at mass flow of 0.5 g/h or more
- b at mass flow of 5.0 g/h or more
- c at mass flow of 25.0 g/h or more

Source: TA Luft, 1986.

Table V. Emission standards in the Federal Republic of Germany
for non-carcinogenic air pollutants: organic matter

Toxics Class and Pollutants	Emission Standard
CLASS I ^a 44 substances	0.02 g/m ³
CLASS II ^b 37 substances	0.10 g/m ³
CLASS III ^c 22 substances	0.15 g/m ³

Notes:

- a at mass flow of 0.1 kg/h or more
- b at mass flow of 2.0 kg/h or more
- c at mass flow of 3.0 kg/h or more

Source: TA Luft, 1986.

Table VI. Emission standards in the Federal Republic of Germany for non-carcinogenic air pollutants: inorganic matter

<u>Toxics Class and Pollutants</u>	<u>Emission Standard</u>
CLASS I ^a Cadmium Thallium Mercury	0.2 mg/m ³
CLASS II ^b Arsenic Selenium Cobalt Tellurium Nickel	1.0 mg/m ³
CLASS III ^c Antimony Manganese Chromium Platinum Copper Palladium Cyanides Rhodium Fluorides Vanadium Lead Tin	5.0 mg/m ³

Notes:

- ^a at mass flow of 1.0 g/h or more
^b at mass flow of 5.0 g/h or more
^c at mass flow of 25.0 g/h or more

Source: TA Luft, 1986.

Table VII. Emission standards in the Federal Republic of Germany for non-carcinogenic air pollutants: gaseous and vaporous inorganics

Toxics Class and Pollutants	Emission Standard
CLASS I ^a Arsine Hydrogen Phosphide Cyanogen chloride Phosgene	1.0 mg/m ³
CLASS II ^b Bromide gases Hydrocyanic acid Chlorine Hydrogen sulfide Fluorine (incl. hydrofluoric acid)	5.0 mg/m ³
CLASS III ^c Chlorine gases and vaporous compounds not included in Class I, including hydrochloric acid	30.0 mg/m ³
CLASS IV ^d Sulfur oxides Nitrogen oxides	5.0 g/m ³

Notes:

- ^a at mass flow of 10.0 g/h or more
- ^b at mass flow of 50.0 g/h or more
- ^c at mass flow of 0.3 kg/h or more
- ^d at mass flow of 5.0 kg/h or more

Source: TA Luft, 1986.