UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

October 18, 1979

MEMORANDUM FOR: Chairman Hendrie
Commissioner Gilinsky
Commissioner Kennedy
Commissioner Bradford
Commissioner Ahearne

FROM: Leonard Bickwit, Jr., General Counsel

SUBJECT: ADEQUATE PROTECTION OF THE HEALTH AND SAFETY OF THE PUBLIC

This is in response to Commissioner Bradford's request, dated March 7, 1979, for a memorandum on the definition of "adequate protection of the public health and safety". He suggested that it would be useful to include a discussion of the meaning of the phrase as it has been used historically in the context of nuclear regulation, as well as any relevant construction of similar language in the statutes of other agencies. This is also in partial response to Commissioner Ahearne's request, dated October 15, 1979, for views on the appropriateness of using economic factors in NRC decisions.

The meaning of "adequate protection" is a recurring issue in nuclear power reactor licensing and regulation. It is faced, at least implicitly, whenever the Commission issues a new substantive regulation, or takes some new licensing action. The most serious questions are presented whenever the Commission decides to impose some new safety improvement on one class of plants, but to "grandfather" others. The Staff frequently "reinterprets" the General Design Criteria in 10 CFR Part 50, Appendix A in light of new knowledge and experience, and then is faced with the difficult task of explaining why the "interpretation" applies only to new plants. Similarly, when the Commission finds under 10 CFR § 50.109 (the backfit rule) that some new safety feature is "required for the public health and safety", how can older plants in operation be exempted from the backfit, but similar plants at the pre-OL stage be covered? How can such distinctions be made without some special consideration being given to "non-safety" factors, such as costs and need for power? The same question arises whenever the Commission is faced with the choice of shutting a plant down or allowing interim generation pending correction of some safety defect or noncompliance item. This memorandum is intended to address the meaning of "adequate protection" and define those matters that may be considered in reaching "adequate protection" decisions. It is designed as a first step in an effort to resolve these recurring issues.

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SUMMARY CONCLUSIONS

Judicial decisions are clear that "adequate protection" is a term that focuses on radiological risk, and is not synonymous with the broad standard "public interest". Accordingly, the Commission could not, in pursuit of adequate protection, engage in some broad inquiry where the public interest lies. On the other hand, judicial decisions, past history and practice, and the practice of other Federal regulatory agencies make clear that adequate protection does not require zero risk. Given this, judicial decisions, logic, and the practice of other Federal agencies support the concept that adequate protection may, in appropriate circumstances, entail at least some balancing of safety against competing considerations. The legislative history of the Reorganization Act strongly suggests that promotion and advancement of the nuclear industry should not be a relevant consideration. Nevertheless, this leaves ample room for the Commission to take into account such factors as economic costs to ratepayers and need for power, provided that protection of the public health and safety is consistently treated as its paramount consideration. Adjudicatory decisions and pronouncements by the Atomic Energy Commission and the Nuclear Regulatory Commission over the years have sometimes indicated to the contrary. In light of the conflicting statements on the question and the considerable importance of the matters at issue, the development of a clear Commission policy statement on safety philosophy would be highly desirable. Since the questions to be addressed would involve broad societal value judgments, interaction with the Congress and the President would be appropriate. One possible course would be for the Commission to develop a proposed statement, seek extensive public comment on it, adopt a final statement as a basis for Commission action and, while operating in accordance with the statement, submit it to the Congress for ratification or modification.

DISCUSSION

A. "ADEQUATE PROTECTION" IN NUCLEAR REGULATION

1. Atomic Energy Act Statutory Language

The Atomic Energy Act of 1954 (the Act) does not specify the precise level of safety that the Commission must assure or the factors that may or should be considered in defining the level of safety. It simply states that applicants for operating licenses must provide such information as the Commission may deem necessary "to enable it to find that utilization or production of special nuclear material will be in accord with the common defense and security and will provide adequate protection to the health and safety of the public."1/ Adequacy is not defined.

1/ Section 182a. This memorandum does not discuss the application of NEPA to safety issues.

In their June 9, 1976 memorandum to the Commission on the scope of the NRC statutory mandate, Peter Strauss and Howard Shapar correctly pointed out that the statutory language by its terms implies that "adequate protection" does not require absolute protection or zero ris Such language as "adequate protection", "unreasonable risk",2/ "minimize danger",3/ and "inimical"4/ ,ives rise to a strong inference that some risks may be tolerated and that something less than absolute protection is required.5/ As will be discussed below, the courts have also held that absolute safety or zero risk is not required, and have interpreted the Act to confer considerable discretion on the Commission to determine what level of protection is adequate or reasonable.

2. Atomic Energy Act Legislative History

The legislative history of the Atomic Energy Act does not provide substantial guidance as to what constitutes adequate protection or the factors that may or should be considered in determining adequate protection. The legislative history of the Act does show that the adequate protection standard is more narrowly focused than some broad "public interest"

2/ The Commission is prohibited from issuing any special nuclear materials licenses if this "would constitute an unreasonable risk to the health and safety of the public." Section 57c(2).

3/ The Commission may issue licenses for facilities to persons "who agree to observe such safety standards to protect health and to minimize danger to life or property as the Commission may by rule establish" Section 103b.

4/ "In any event, no license may be issued to any person within the U.S. if, in the opinion of the Commission, the issuance of a license would be inimical to the ... health and safety of the public." Section 103d.

5/ In Power Reactor Development Co. v. Electrical Union (PRDC), 367 U.S. 396 (1961) the Court focused on the "adequate protection" statutory standard as opposed to the various other statutory safety standards such as "unreasonable risk". However, there is no basis in the Act or its legislative history for distinguishing between the various statutory standards, and the Commission has construed them all as amounting to the same thing. Maine Yankee Atomic Power Company (Maine Yankee Atomic Power Station), ALAB-161, 6 AEC 1003, 1009 (1973).

or "public convenience and necessity" standard.6/ However, there is no helpful guidance beyond this. Furthermore, no unambiguous picture of adequate protection emerges from the over 25 years of Congressional oversight hearings or legislative history of the various amendments to the Act. For example, during hearings on the bill that was to become the Energy Reorganization Act, where questions were raised as to how or whether the AEC took economic costs into account in making safety determinations, the questions were answered differently by different persons. When Senator Ribicoff asked AEC Director of Regulation L. Manning Muntzing whether the AEC "ever allow[ed] cost to stand in the way of installing the newest safety and safeguard devices," Muntzing responded:

> [T]he AEC is charged with assuring the reasonable safety of the facilities it licenses and for that reason, the first decision is made with regard to safety. If it costs additional money, it costs additional money. The cost-benefit relationship

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6/ In the Joint Committee on Atomic Energy's report on the measure, facility licensing under section 103 was described as "subject to regulation by the Commission in the interest of the common defense and security and in order to protect the health and safety of the public," and the Commission was "required to issue licenses to all qualified applicants without other discretion on its part." S. Rep. No. 1699, 83rd Cong., 2d Sess. (1954) and H.R. Rep. No. 2181, 83rd Cong., 2d Sess. (1954) at 20, I Leg. Hist. Atomic Energy Act of 1954 768, 1016. In a separate statement that is part of the Joint Committee's Report, Representatives Holifield and Price criticized the Committee bill because the licensing standards were "barren of any recognition of the public interest in securing electric energy from this new resource at the lowest possible rates." Id. at 121, I Leg. Hist. Atomic Energy Act of 1954 869, 1117. They believed that the Federal Power Commission's advice during the hearings that "the grant of the (license) privilege should depend not solely on the negative consideration that national defense will not be harmed, but on the affirmative ground of benefit to the public interest in electric power," should have been followed. Supra at 123, I Leg. Hist. Atomic Energy Act of 1954 871, 1119. Views similar to those expressed by Representatives Holifield and Price were also expressed by Senator Gore of Tennessee during Senate debates on the measure prior to passage. III Leg. Hist. Atomic Energy Act of 1954 3454. However, the bill was enacted with the "negative" licensing standards intact.

> is evaluated, however, as part of the environmental impact statements that are prepared ... if it requires backfitting, then it will be done. Essentially, however, it is very important that we put safety first. We know that this brings economic penalties, but those are things that must be borne .... 7/ (emphasis supplied)

AEC Commissioner (later NRC Chairman) William A. Anders immediately qualified Muntzing's suggestion that costs were not taken into account. He said:

> When one speaks of costs, it would be irresponsible not to balance the gain from the incremental improvement in safety against the incremental cost of this improvement. And when people bring up the word "costs", immediately dollar signs flash into one's mind. But the costs that AEC is particularly concerned about are the various social and environmental costs that could result from a lack of power. 8/ (emphasis supplied)

3. Judicial Decisions

Two judicial decisions, New Hampshire v. AEC 9/ and Cities of Statesville v. AEC 10/ held that the Commission's regulatory jurisdiction under the Atomic Energy Act is essentially confined to radiological health and safety and common defense and security matters, and does not extend broadly to matters of the public interest. Neither case deals with how "adequate protection" is to be ascertained.

Power Reactor Development Company v. Electrical Union 11/ ("PRDC") involved a challenge to the AEC's grant of a provisional construction permit for the construction of a fast breeder reactor near Detroit, Michigan. The permit was granted without resolving several serious safety issues, including the issue whether the plant should be designed to withstand a melt-down of the reactor core. Rather, such matters were left for resolution at the operating license

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7/ Legislative History of the Energy Reorganization Act of 1974, Vol. III at 3572.

8/ Id. at 3574.

9/ 406 F.2d 170 (1st Cir. 1969), cert. denied, 395 U.S. 962 (1969).

10/ 441 F.2d 962 (D.C. Cir. 1969).

11/ 367 U.S. 396 (1961).

stage. Intervenors claimed, among other things, that the same safety standard or "degree of certitude" should have been applied by the AEC at the construction permit stage as would be applied at the operating license stage. The Court of Appeals for the D.C. Circuit agreed and vacated the AEC's grant of the permit, and the Government appealed. The Supreme Court stated that there was "no doubt that construction permits, like all other licenses can be issued [under the Act] only consistently with the health and safety of the public," 12/ but held that the AEC could defer a definitive safety finding until the operating license stage, and rejected petitioner's argument. In doing so, the Supreme Court stated as follows:

> We deem it appropriate to add a few words concerning the fears of nuclear disaster which respondents so urgently place before us. The respondents' argument is tantamount to an insistence that the Commission cannot be counted on, when the time comes to make a definitive safety finding, wholly to exclude the consideration that PRDC will have made an enormous investment. The petitioners conceded that the Commission is absolutely denied any authority to consider this investment when acting upon an application for a license for operation. PRDC has been on notice long since that it proceeds with construction at its own risk, and that all its funds may go for naught. With its eyes open, PRDC has willingly accepted that risk, however great ....
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> It may be that an operating license may never be issued ....
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> This is the multi-step scheme which Congress and the Commission have devised to protect the public health and safety. We hold that the actions of the Commission up to now have been within the Congressional authorization. We cannot assume that the Commission will exceed its powers, or that these many safeguards to protect the public interest will not be fully effective. 13/

The language "absolutely denied the authority" is strong, raising the question whether the Court's opinion should be read as holding that the Commission may never consider

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12/ Id., at 404.

13/ Supra, note 11 at 414-416.

economic impacts when making safety judgments under the Atomic Energy Act. For several reasons this does not appear to be a reasonable reading. First, the construction permit was issued with several major safety issues unresolved. The opinion does not address the question of whether consideration of the applicant's investment would have been precluded had this issue been resolved at the construction permit stage (a "definitive" finding made) and the AEC were seeking a plant modification at the operating license stage.14/ Second, the opinion does not address the question of the extent to which economic or other impacts can be considered either in promulgating safety standards, or in reaching judgments on individual cases with significantly differing fact situations. Most importantly, it is reasonably clear from the AEC's final opinion in the PRDC case that the crucial aspect of the decision turned upon a balancing or accommodation by AEC between the needs of a developing nuclear power technology and the needs of sound regulation.15/ Such a balance or accommodation was responsible for the basic AEC decision to allow the project to proceed notwithstanding the absence of data regarding such matters as core-melt accidents. The nature of this balance or accommodation was not discussed in the Supreme Court's opinion. Nevertheless, while the PRDC case can be distinguished from many fact situations where "non-safety" factors might be taken into account, the underlying tone of the PRDC opinion, and the strong statements made by AEC in the case that public safety is the "first, last, and a permanent consideration", counsel against any approach that would give equal weight to safety and "non-safety" factors in every safety decision.

Some explicit judicial endorsement of balance or accommodation along the lines implicit in PRDC is set forth in Siegel v. AEC.16/ In Siegel, the Court upheld the AEC's regulations in 10 CFR § 50.13 excluding foreign enemy attacks from the category of incidents that nuclear power plants should be designed to withstand. In reaching its conclusion, the Court stated as follows:

14/ However, in an early "Memorandum" in the PRDC case, the AEC implied in dicta that consideration of the applicant's investment would have been precluded even if the permit had not been a "provisional" one (i.e., a "definitive" finding made) 1 AEC 11, 12 (1956). The AEC in its final decision in the PRDC case emphasized that safety was the "first, last, and a permanent consideration". 1 AEC 72 (1958).

15/ 1 AEC 128 (1959). See also, the discussion in the Covernment's brief before the Court at p. 45.

16/ 400 F.2d 778 (D.C. Cir. 1968).

> What the Commission has essentially decided is that to impose such a burden would be to stifle utterly the peaceful utilization of atomic energy in the United States. Such a decision hardly seems to us to conflict with the Congressional purposes underlying the Act, nor to exceed the scope of the authority given the Commission by Congress to realize those purposes.17/

Here there is some indication that impacts on the nuclear power industry may be considered in determining adequate protection. Moreover, the Court in Siegel stressed the broad authority vested in the Commission in carrying out its mission to protect health and safety and common defense and security:

> In the Presidential Message recommending the legislation which culminated in the Atomic Energy Act of 1954, it was said that flexibility was a peculiar desideratum and that, absent an accumulation of experience with the new civilian industry hopefully to be brought into being, "it would be unwise to try to anticipate by law all of the many problems that are certain to arise." ... Congress agreed by enacting a regulatory scheme which is virtually unique in the degree to which broad responsibility is reposed in the administering agency, free of close prescription in its charter as to how it shall proceed in achieving the statutory objectives.18/ (emphasis supplied)

Northern States Power v. Minnesota19/ also supports the proposition that in defining adequate protection the Commission may balance improvements in safety and progress in use of nuclear energy. In Northern States Power the Court held that the States were preempted by the Act from imposing limits on liquid radioactive discharges from nuclear power plants. In so holding, the Court stated that:

> Congressional objectives expressed in the 1954 Act evince a legislative design to foster and encourage the development, use and control of atomic energy so as to make the maximum contribution to the general welfare and to increase the standard of living. 42 U.S.C. §§ 2011, 2012. However, these objectives were to be effectuated "to the maximum extent consistent with the common defense and security and with the health and safety of the public." 42 U.S.C.

17/ Id. at 783-784.

18/ Supra, note 16 at 781.

19/ 447 F.2d 1143 (8th Cir. 1971), affirmed, 405 U.S. 1035 (1972).

§§ 2013. Thus, through direction of the licensing scheme for nuclear reactors, Congress vested the AEC with the authority to resolve the proper balance between desired industrial progress and adequate health and safety standards. Only through the application and enforcement of uniform standards promulgated by a national agency will these dual objectives be assured. Were the states allowed to impose stricter standards on the level of radioactive waste releases discharged from nuclear power plants, they might conceivably be so over-protective in the area of health and safety as to unnecessarily stultify the industrial development and use of atomic energy for the production of electric power.20/ (Emphasis added)

The District Court decision in Nader v. Ray also recognizes some kind of balancing process:

> Absolute certainty or "complete," "entire," or "perfect" safety is not required by the Atomic Energy Act, nor does nuclear safety technology admit of such a standard. Power Reactor Development Co. v. Int'l Union, Electrical Workers, supra; cf., Crowther v. Seaborg, 312 F.Supp. 1205, 1234 (D. Colo. 1970). The Supreme Court recognized in the Power Reactor case that nuclear technology is subject to change. 367 U.S. at 408, 81 S.Ct. 1529, 6 L.Ed.2d 924. What constitutes "reasonable assurance of adequate protection" is also subject to change, as the state of the nuclear safety art advances. Cf., Crowther v. Seaborg, supra. It is for the Commission to weigh the state of that art, the risk of accidents, the record of past performance, the need for further improvement in nuclear safety matters, and other considerations. Balancing these factors calls for the exercise of discretion by the expert agency in a judgmental process that is very different from the kind of "clear, nondiscretionary legal duty" to comply with the procedural requirements of the National Environmental Policy Act that the court referred to in Izaak Walton League of America v. Schlesinger, 337 F.Supp. 287, 291 (D.D.C. 1971).21/ (Emphasis added)

Finally, several judicial decisions follow Siegel in stressing the broad discretion given the Commission in carrying out its statutory mandate to assure adequate protection.22/

20/ Id. at 1153-1154.

21/ 363 F.Supp. 946, 954-955 (D.C.D.C. 1973)

22/ Union of Concerned Scientists v. AEC, 499 F.2d 1066 (D.C. Cir. 1974); North Anna Environmental Coalition v. NRC, 533 F.2d 655 (D.C. Cir. 1976); Public Service Company of New Hampshire v. Nuclear Regulatory Commission, 582 F.2d 77 (1st Cir. 1978).

4. Energy Reorganization Act

The Energy Reorganization Act of 1974 does not, by its terms, amend any of the substantive public health and safety and common defense and security standards set forth in the Atomic Energy Act or set forth any new standards. The House Committee Report specifically stated that "the Commission will continue to carry out those [regulatory] functions under pertinent provisions of the Atomic Energy Act of 1954, as amended ....23/ However, a major purpose of the Energy Reorganization Act of 1974 was to separate the "developers" from the "regulators".24/ This was emphasized in the Senate Report which, in describing the applicability of sections 1, 2, and 3 of the Act, states that "all references to encouraging, promoting, utilizing, developing and participating in atomic energy or the atomic energy industry shall not be applicable to the [Commission]."25/ It could be argued that consideration of such matters as economic costs, need for power, and development of the industry would be exercising some "promotional" function contrary to the intent of Congress.

As the discussion above indicates, any balancing judgment would be the exercise of a regulatory function in its purest sense -- not the exercise of some "promotional" function. While the Reorganization Act may fairly be read to rule out any NRC disposition to favor or promote nuclear power as opposed to other energy sources in its regulatory decisions, more neutral consideration of impacts on electric power ratepayers and energy supply are not clearly ruled out by the statute or the legislative history.

Thus, we believe that consideration of such factors as economic costs to consumers and energy supply would not be prohibited by the Reorganization Act. It is a reasonable

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23/ H.R. Rep. No. 93-707, 93rd Cong., 1st Sess. (1973) at 22, I Leg. Hist. Energy Reorganization Act of 1974 413. There is no indication of any contrary intent in the legislative history.

24/ Section 2(c) of the Energy Reorganization Act of 1974, as amended. See also, S. Rep. No. 93-980, 93rd Cong. 2d Sess. (1974) at 2, 19, 27, II Leg. Hist. 965, 982, 990; H.R. Rep. No. 93-707, 93rd Cong., 1st Sess. (1973) at 4, I Leg. Hist. at 395.

25/ S. Rep. No. 93-980 at 83, 93rd Cong., 2d Sess. (1974), II Leg. Hist. Energy Reorganization Act of 1974 1046.

inference from the legislative history of the Energy Reorganization Act of 1974 that the regulation of nuclear energy was to be enhanced not by imposing different statutory standards, but by establishing a separate agency to perform a purely regulatory mission.

5. Agency Practice

The underlying nature of the adequate protection standard has been addressed in only a few adjudicatory decisions. The most definitive is Maine Yankee Atomic Power Company (Maine Yankee Atomic Power Station).26/ In Maine Yankee, the Appeal Board, speaking for the Commission, stated the matter at issue and the conclusion thereon as follows:

> Broadly stated, from what can be gleaned from its brief and oral argument, the Joint Intervenors' position seems to come down to this: While the Commission's regulations reflect what it regards as adequate to protect the public health and safety, they impose only minimum standards which must be met by all licensees. In each individual case, there must be an assessment of the risks which remain despite compliance with all applicable regulations. If that assessment produces the conclusion (said to be required by the stipulation here) that there is "some degree of [residual] risk," it must be weighed against the benefits expected to flow from the operation of the facility. Only if the Licensing Board finds, upon striking the balance, that the risk is acceptable can it make the "reasonable assurance" and "not inimical" determinations. In this instance, according to Joint Intervenors, there was insufficient evidence of benefit to have enabled the Board, had it done such balancing, to make a finding of acceptability.
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> In substantial measure, the Joint Intervenors' thesis respecting the ingredients of the "reasonable assurance" and " not inimical" standards runs counter, we believe, to the normal import of the terms used by Congress and the Commission in their formulation of those standards. It is difficult to distill the "acceptability" concept developed by the Joint Intervenors from such language as "adequate protection to

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26/ 6 AEC 1003 (1973). See also Columbia University, 4 AEC 849, 862-863 (1972); Public Service Company of Colorado (Fort St. Vrain Nuclear Generating Station), 4 AEC 214, 216 (1969).

> the health and safety of the public" (Section 182a of the Act) or "reasonable assurance [that the facility can be operated] without endangering the health and safety of the public" (10 CFR 50.57(a)(3)(i)). The decision as to whether a threat to health and safety is posed by any particular activity obviously does entail an assessment of the nature and extent of the risks involved. But the quantum of protection to, or endangerment of, public health and safety is not dependent likewise upon how much benefit will be obtained from the activity. In the present context, a specific nuclear power facility is no safer because it is needed and, by the same token, is no more endangering to health and safety because it might be dispensable.
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> We therefore hold that, in making its ultimate safety findings, the Licensing Board was not called upon to undertake any independent risk/benefit analysis. The Board's function was, rather, to ascertain whether, irrespective of how great or small might be the benefits flowing from the operation of this particular facility, the record established that the health and safety of the public would be adequately protected and that the licensing of the facility would not be inimical to it. As previously noted, the Board resolved these questions in the applicant's favor on the dual bases that the evidence demonstrated that the reactor would comply with applicable Commission regulations and that, in this instance, the Joint Intervenors had not shown that the regulations were inadequate to protect public health and safety. We now consider whether that resolution was correct.27/ (Emphasis added)

This decision, unless overturned by the Commission, holds that adequate protection under the Act is measured solely by the nature and extent of the risk, and that the amount of the benefits associated with plant operation can play no role in safety decisions under the Act. While the decision does not address the role of economic costs, a reasonable inference from the decision is that this factor would also be irrelevant in determining adequate protection.

27/ 6 AEC at 1006, 1008.

One other AEC decision, Department of Water and Power of the City of Los Angeles (Malibu Plant),28/ is worthy of note. In Malibu the Commission (AEC) remanded a Licensing Board decision authorizing the grant of a construction permit for a nuclear power plant located near an active earthquake fault and directed the Board to include protection against ground displacement into the plant design. It was generally understood that this remand had the effect of denying the application since protection against ground displacement was not within the state of the art. Implicit in the decision is the concept that adequate protection may in some cases require denial of an application despite the fact that the application incorporates everything technically feasible to reduce safety risks.

The Commission's regulations carry the adequate protection standard one small step forward by adopting the concept of "reasonable assurance"29/, which perhaps more clearly than the statutory standard conveys the concept that zero risk is not necessary. However, it is difficult to distill from the regulations any further concept of adequate protection which has universal application. To be sure the regulations do in a collective sense embody what is necessary to provide adequate protection. The difficulty is that the regulations are not specifically based on any single underlying concept of adequate protection, and the associated rulemaking records (which for the most part date back into the 1960's and early 1970's) consist largely of conclusory statements.

However, if one examines 10 CFR Parts 20 and 100, it is possible to extract two concepts of adequate protection that seem to have reasonably broad application. First, 10 CFR Part 100 has had the effect of requiring the incorporation of safety features to prevent the occurrence only of "credible" accidents or to mitigate the consequences of "credible" accidents.30/ Beyond this reference, there is no generalized statement in 10 CFR Part 100 regarding the kinds of risks which must be protected against, and there is no explicit reference to risk-benefit balancing. Thus we have a general concept of adequate protection as applied to accidental releases -- that protection does not need to be provided for "non-credible" accidents, but that no expense will be spared to prevent the occurrence of credible accidents or to mitigate their consequences (to less than 300 rem to the thyroid or

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28/ 3 AEC 179 (1967).

29/ 10 CFR §§ 50.35(a)(4), 50.40(a), 50.57(a)(3).

30/ 10 CFR § 100.11, particularly note 1.

25 rem to the whole body). There is no discussion in the Part 100 rulemaking record of how the AEC translated adequate protection into protection against credible accidents. In particular, there is no discussion of the role need for power, economic costs, or impacts on the industry may have played in the decision.

This "credible accident" concept has given rise to some problems. For example, the regulations do not provide any guidance as to which accidents are credible and which are not, although accident probability is clearly the determining factor. Also, in virtually all areas the "credible accident" requirement of Part 100 overlaps with one or more elements of the General Design Criteria in Part 50, Appendix A. The General Design Criteria do not generally adopt any credible/non-credible distinction in dealing with accidents. It is unclear whether a plant system can comply with Part 50 and not comply with Part 100. It is also unclear whether the credible/non-credible distinction is applicable to natural phenomena, such as earthquakes and floods. Thus, the concept may not be necessarily applicable to all accidents.

In contrast to Part 100, the limits on routine, planned releases of radioactive materials in Part 20 have always been based on an explicit balancing of factors. The basic limits in 10 CFR §§ 20.105 and 20.106 are based on a balancing of the biological risks from radiation and the benefits derived from radiation use,31/ and the requirement that releases be kept as low as reasonably achievable is designed to take economic and other costs explicitly into account in setting permissible release limits.32/

The so-called "backfit rule" in 10 CFR § 50.109 further complicates the situation. The rule authorizes the Commission to require additional safety features beyond those required at the construction permit stage if this would "provide substantial additional protection which is required for the public health and safety." This rule, and the general Commission approach to "backfit" matters came under detailed scrutiny

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31/ Federal Radiation Council Staff Report No. 1, May 13, 1960.

32/ See 10 CFR Part 50, Appendix I. The criteria used by NRC to approve consumer products containing radioactive material that are to be exempt from licensing also specifically provide for consideration of "non-safety factors". The policy on this matter is that the decision turns on a balancing of the radiation hazards and benefits or usefulness of the product to the public. "Use of Byproduct Material and Source Material", 30 FR 3462 (March 16, 1965).

by the Joint Committee on Atomic Energy (JCAE) in 1976 when one NRC and three GE engineers resigned and raised several serious reactor safety questions. The JCAE hearings are important because in order to respond to the safety questions that were raised the NRC staff was required, for the first time, to articulate a position on the role of economic costs in making safety decisions. In the course of explaining why some older reactors lacked some of the safety features included in newer reactors, the Director of NRR (with implicit Commission approval) articulated the role of costs and benefits in reactor safety reviews as follows:

> In determining whether a safety issue warrants backfitting to older plants, a judgment is made first of the safety significance. This judgment is based on technical considerations only, and is not influenced by political or economic factors. Once a position defining an acceptable level of safety is established by both quantitative and judgmental processes, backfitting action is initiated, as appropriate, to assure that at least that level of safety is achieved. Further safety improvements are then evaluated considering the value of the added safety as well as the economic or other impact of the requirement.33/

This formulation does not address how the minimum "acceptable level of safety" referred to in the testimony is established. Moreover, this effort by the Commission to explain its review philosophy is not consistent with the Commission's Maine Yankee and other adjudicatory decisions. It is quite clear from these decisions that once compliance with the regulations is demonstrated, it necessarily follows, absent some special showing, that the adequate protection standard is met, and that the economic costs or other "non-safety" impacts of safety improvements are irrelevant. Yet under the safety

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33/ "Investigation of Charges Relating to Nuclear Reactor Safety", JCAE Hearings, February and March, 1975 at 323. It should be noted that it has long been the NRC (and AEC's) policy to consider economic factors in choosing among two or more safety requirements, all of which present the same safety risk reduction. This is made clear, for example, in the NRC's present value-impact guidelines. The issue addressed in this memorandum deals with the different situation where the choices facing NRC entail different safety risks, and where "trade-offs" between safety and non-safety factors could occur.

approach taken by the Commission during the 1976 hearings, the Commission may require additional improvements not required in order to comply with the regulations, so long as the increase in protection is worth the cost. This would come as a surprise to many intervenors, who are routinely informed in the Commission's adjudicatory proceedings that proposals for such additional safety features as "core catchers" may not be considered in licensing hearings simply because they are not required in order to meet the Commission's regulations. However, the approach taken in the 1976 JCAE hearings is the current approach taken by the staff when confronted with grandfathering or backfit questions.

The first successful attempt to define adequate protection in the sense of an overall safety goal occurred in 1973 with the publication of WASH-1270, "Anticipated Transients Without Scram for Water-Cooled Power Reactors". In this report the Staff adopted the overall safety objective that the risk to the public from all nuclear reactors occurrences should be very small compared to most other risks of life. The considerations that led to this goal were not explained. This goal would in the Staff's view be met if accidents with radiological consequences in excess of 10 CFR Part 100 guidelines (300 rem to the thyroid, 25 rem whole body) have an average recurrence interval of at least 1000 years for all nuclear plants combined. For 1000 operating plants, this goal would be satisfied if there is no greater than one chance in one million per year for a nuclear power plant to have a serious accident with consequences in excess of Part 100. The Staff was careful to point out in the report that the above was merely a goal, and not a fixed requirement, in view of the difficulty of determining the likelihood of occurrence of low probability accidents. The goal was not incorporated into any Commission regulation, policy statement, or adjudicatory decision, and there are to this date continuing discussions of the goal in the context of further evaluations of anticipated transients without scram.34/

34/ This safety goal is reflected in Section 2.2.3 of the NRC Standard Review Plan, which indicates that design basis events resulting from presence of hazardous materials or activities in the plant vicinity include "each postulated type of accident for which the expected rate of occurrence of potential exposures in excess of the 10 CFR Part 100 guidelines is estimated to exceed the NRC staff objective of approximately 10^{-7} per year." The 10^{-7} figure is developed by deciding that the risks posed by offsite hazards should not contribute more than one-tenth of the overall risk. See also Section 3.5.1.6 "Aircraft Hazards". For the most part, however, the Standard Review Plan does not make use of particular probability numbers.

B. RELEVANT LANGUAGE IN THE STATUTES OF OTHER AGENCIES

1. Consumer Product Safety Commission (CPSC)

The safety obligations of the CPSC are largely spelled out in its governing statute. Consumer products may be banned only if no safety standard would "adequately protect the public from the unreasonable risk of injury associated with such product."35/ Such safety standards as are promulgated must be "reasonably necessary to prevent or reduce an unreasonable risk associated with a product."36/ The CPSC, in promulgating any safety rule, "shall express in the rule itself the risk of injury which the standard is designed to eliminate or reduce."37/

The courts have taken the position, based upon the clear legislative history of the statute, that Congress intended the Commission to make the judgment whether a particular risk was "unreasonable,"38/ and that the reasonableness of risks is to be assessed in part by considering the economic impact of any safety standard imposed. In the Aqua Slide 'N' Dive case, the Fifth Circuit Court of Appeals observed:

> The necessity for the standard depends upon the nature of the risk, and the reasonableness of the risk is a function of the burden a standard would impose on the user of a product.39/

The court reiterated the definition of "unreasonable risk" formulated by the D.C. Circuit in Forester v. CPSC, in which the court stated that a finding of unreasonable risk under the Federal Hazardous Substances Act involved:

> a balancing test like that familiar in tort law: the regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm

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35/ 15 U.S.C.A. §§ 2057(2).

36/ 15 U.S.C.A. § 2051(b)(1)(2).

37/ 15 U.S.C.A. § 2058.

38/ See, Aqua Slide "N" Dive v. Consumers Product Safety Commission, 569 F.2d 831 (1978); Forester v. CPSC, 559 F.2d 774 (D.C. Cir. 1977).

39/ 569 F.2d at 839.

the regulation itself imposes upon manufacturers and consumers.40/

2. Food and Drug Administration (FDA)

The mandate of the Food and Drug Administration varies depending on the type of hazard involved. Attachment 1 to this paper is a table, prepared for the FDA, listing a number of laws administered by it (as well as statutes administered by the CPSC, EPA, and the Agriculture Department) and the factors to be taken into account under each statute.

If the CPSC is an example of an agency required to take cost considerations into account, and the NRC an agency whose statute leaves the relationship between safety and costs at best extremely vague, the Food and Drug Administration, in one of its areas of responsibility, has a uniquely explicit Congressional directive that certain risks are unacceptable, irrespective of costs. The Delaney Clause, enacted in 1958, provides that no food additive can be used that induces cancer in man or animals when ingested, or in animals after appropriate safety tests.41/ This emphasis on eliminating risks without regard to economic considerations applies generally through the sections of the Food and Drug Act dealing with food purity. The laws regarding foods are not wholly consistent in their approach, however. The Delaney Clause, which is a reflection of the public's awareness and special fears of the hazards of cancer, does not prohibit the use of possibly harmful substances used historically with FDA or Agriculture Department approval before 1958 (such as nitrites); nor does it prohibit sale of foods in which carcinogenic substances inevitably occur despite good manufacturing processes (such as aflatoxin in peanut butter).

In other areas, the FDA has greater flexibility. In certifying drugs as to their safety, the agency may weigh the risks involved against the drug's potential benefits. In a case involving a false advertising claim against a weight reduction clinic, the Court of Appeals for the Ninth Circuit recently observed:

> Considerations of safety and effectiveness cannot be wholly separated, since many risky medical procedures may be regarded by the FDA as "safe," in light of their greater potential benefits.42/

40/ 559 F.2d at 789.

41/ 21 U.S.C.A. 301 et seq.

42/ FTC v. Simeon Management Corp., 532 F.2d 708, 714 (1976).

3. Environmental Protection Agency (EPA)

The Environmental Protection Agency administers a number of statutes, with a variety of mandates. Two of them -- the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 43/ and the Toxic Substances Control Act 44/ -- require the balancing of risks and benefits. Under FIFRA, a pesticide may be "cancelled" if the agency finds "unreasonable risk to man and the environment, taking into account economic, social, and environmental costs."45/ Cancellation proceedings are often quite lengthy -- several years or more -- and the sale and use of the pesticide in question may continue until the proceedings are completed. If, however, the agency finds an "imminent hazard" to human health from the use of the pesticide during the pendency of the cancellation proceeding, it may "suspend" its production and sale. In either case, it must assess the risks and the benefits involved.

The Toxic Substances Control Act presents a similar statutory framework. The statute and its legislative history make clear that risks and benefits are to be weighed in protecting the public against toxic substances. The law states Congress' intent that "the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act."46/

Certain provisions of the Federal Water Pollution Control Act and Clean Air Act require that ambient air and water quality standards be set based only on health or environmental effects without reference to costs or benefits.47/ However, these provisions apparently reflect a Congressional belief that there was a "safe threshold" for the air and water pollutants involved, and that a standard could be set that would provide for essentially zero risk without massive economic impacts. More relevant are the provisions of these two Acts relating to control of hazardous or toxic pollutants for which there is no safe threshold. The statutes here call for emission standards which will provide an "ample margin of safety to protect the public health", and do not expressly authorize

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43/ 7 U.S.C.A. 136 et seq.

44/ 49 U.S.C.A. 1801-12.

45/ See EDF v. EPA, 548 F.2d 998 (D.C. Cir. 1977).

46/ 15 U.S.C.A. 2601.

47/ 42 U.S.C.A. 7409; 33 U.S.C.A. 1313.

consideration of factors other than health and environmental effects.48/ Nevertheless, EPA has construed the statutes in question as authorizing a balancing of factors in promulgating standards. In reaching this conclusion, EPA reasoned that if Congress had intended the drastic results in terms of economic dislocations that would result from zero risk it would have spoken with much greater clarity in the law, that therefore zero risk was not necessarily to be achieved, and that if some risk was to be accepted, then at least limited consideration of factors other than the level of risk itself was unavoidable.49/

4. Other Agencies and Statutes

Under the Hazardous Materials Transportation Act, the Secretary of Transportation is given broad discretion to assure "adequate" protection against "unreasonable risk to health and safety."50/ DOT's implementing regulations do not indicate how "unreasonable" is defined. Rather, they simply indicate what substances and packaging are and are not acceptable for transport.51/

The Administrator of the Federal Aviation Administration is obligated by the Federal Aviation Act to prescribe "such reasonable rules and regulations ... as the Administrator may find necessary to provide adequately for national security and safety in air commerce."52/ Adequacy is not defined, although the Director is instructed to give "full consideration to the duty resting upon air carriers to perform their services with the highest possible degree of safety in the public interest."53/ The courts have found this statute to give considerable discretion to the Administrator to assess hazards and determine the reasonableness of suggested remedial action. In one case, the D.C. Circuit rejected a claim by Ralph Nader that to fulfill his statutory mandate, the Administrator was obligated to ban smoking on airplanes, in light of the added danger of fire created by passengers' smoking.54/ The court did not find in the Administrator's

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48/ 42 U.S.C.A. 7412; 33 U.S.C.A. 1317.

49/ See 42 FR 28154 (June 2, 1977).

50/ 49 U.S.C.A. 1801 et seq.

51/ 49 CFR Parts 171, 173.

52/ 49 U.S.C.A. 1421(a).

53/ 49 U.S.C.A. 1421(b).

54/ Nader v. FAA, 440 F.2d 292 (1971).

action any assertion that the claim of hazard was necessarily groundless; nevertheless, he possessed discretion to make judgment as to the magnitude of the asserted risk. The decision indicates that the statutory mandate of the "highest possible degree of safety" is not as absolute as it may appear.

The mandate in the Atomic Energy Act to provide adequate protection to the health and safety of the public falls somewhere in between the so-called Delaney Clause, with its emphasis on eliminating cancer risks without regard for economic cosiderations, and FIFRA and the Toxic Substances Control Act, where Congress specifically directed EPA to consider the economic and social impact of actions taken under those Acts. Unlike the Delaney Clause, the Atomic Energy Act does not require zero risk, even as a goal. On the other hand, unlike FIFRA and the Toxic Substances Control Act, there is no specific direction in the Atomic Energy Act to take economic or other "non-safety" factors into account. The closest analogy is probably to those portions of the Clean Air Act and Federal Water Pollution Control Act which require that standards be set for toxic pollutants that provide an "ample margin of safety to protect the public health". Here EPA has construed its statutes as authorizing consideration of "non-safety" factors such as economic costs in standard setting. A review of the other statutes does reveal that over the years the Congress has become increasingly specific as to the factors it believes regulatory agencies should take into account in decisionmaking. The Atomic Energy Act was enacted well before this trend developed at a time when the Congress was much more willing than today to vest broad discretion in an agency free of any specific direction as to the factors to be considered in decisionmaking.

CONCLUSIONS

Judicial decisions are clear that "adequate protection" is a term that focuses on radiological risk, and is not synonymous with the broad standard "public interest". Accordingly, the Commission could not, in pursuit of adequate protection, engage in some broad inquiry where the public interest lies. On the other hand, judicial decisions, past history and practice, and the practice of other Federal regulatory agencies make clear that adequate protection does not require zero risk. Given this, both judicial decisions and logic support the concept that adequate protection entails at least some balancing of safety against competing considerations. The legislative

history of the Reorganization Act strongly suggests that promotion and advancement of the nuclear industry should not be a relevant consideration. Nevertheless, this leaves ample room for the Commission to take into account in appropriate circumstances such factors as economic costs to ratepayers and need for power provided that protection of the public health and safety is consistently treated as its paramount consideration.

A number of meanings of "adequate protection" could be proposed. It would not be inconsistent with the type of balancing discussed in this memorandum to state that some risks (for example, operation of a reactor near an active earthquake fault, as in the Malibu case) are so severe that no reasonably foreseeable economic cost or need for power impact could prevail over the risk, but that the acceptability of other lesser risks depends on consideration of economic costs or impacts on energy supply. This would involve a two-tiered approach to adequate protection, under which, for example, grandfathering of new safety requirements would be permissible in the "second" safety tier but not in the first. This type of approach would be consistent with the general thrust of the PRDC case and the holding in the Malibu case, because it would reflect a Commission belief that certain safety risks are simply unacceptable, even taking into account all the ordinary "non-safety" factors that may be involved. Alternatively, one could adopt the view that there is a wide spectrum of safety risks, with "non-safety" factors given greater weight as one moves from the more severe to the less severe hazards. So long as safety assumes a paramount importance and "non-safety" factors are given little or no weight as one moves from the minor safety risks to the more severe safety hazards, this "spectrum" approach would also be consistent with the tone of PRDC and Malibu.

The Commission could as a matter of policy confine its use of the "adequate protection" standard to dealing with the more severe safety risks, where ordinary economic or other "non-safety" arguments would be given little or no weight, and rely on the authority in section 161b. of the Atomic Energy Act to issue rules or orders to "minimize danger to life or property" in dealing with lesser risks where balancing judgments would be permitted. In this way a "two tier" safety standard would be related to two tiers of statutory standards. The "minimize danger" provision has been completely unexplored in past decisions, regulations, and practice as a possible basis for making safety judgments. The conclusion that some Commission safety judgments may properly entail a balancing among competing considerations does not depend on the two words "adequate protection", but

depends rather on the structure of the Act as a whole, and the Commission may properly look to the Act as a whole in establishing a safety philosophy.

There is one class of safety decisions for which consideration of non-safety factors would present significant litigative risk in light of the PRDC case. This class would consist of decisions at the operating license stage on safety matters that could in theory have been but were not resolved at the construction permit stage. Here the Supreme Court language that the NRC is "absolutely denied" the authority to consider the utility's investment (see pages 5-7) should be taken into account, perhaps by adopting the policy that non-safety factors will only be considered to the extent that they would have been relevant at the construction permit stage, with the status of completion of the plant given no consideration. Beyond that category of decisions, however, and subject to the principle that protection of the public health and safety is the "first, last and a permanent consideration" under the Atomic Energy Act, the Commission has considerable discretion to determine how it will consider competing interests in reaching safety judgments.

If the Commission were to explicitly adopt some balancing test for adequate protection that took into account such things as economic costs and need for power, then Maine Yankee would need to be overturned or severely limited. The Commission would also be faced with the question whether to permit case-by-case balancing judgments, as described in the 1976 JCAE hearings, or to restrict balancing judgments to generic proceedings. Permitting case-by-case balancing judgments would afford maximum flexibility to the Commission to require incorporation of the best available safety technology. And, so long as the focus of the case- specific balancing judgments is on safety improvements beyond those required to achieve minimum compliance with Commission regulations, the case-by-case approach would be consistent with the concept generally embodied in the Atomic Energy Act that the nuclear industry should be subject to a system of uniform national safety standards. The difficulty with this approach is that licensing reviews and hearings may become involved in unbounded examinations of the costs and benefits of different safety systems. Applicants in full compliance with the regulations will have no assurance that the plant design is satisfactory without conducting a NEPA-type cost/benefit analysis of additional safety improvements.

If balancing judgments were reserved for Commission decisions on safety standards, the licensing review process could con-

tinue as at present. However, the Commission would have to modify the "backfitting" concept adopted during the 1976 JCAE hearings, and some flexibility might be lost. A special case would need to be made for enforcement matters, where the Commission would likely wish to choose from a range of enforcement actions in dealing with safety defects or items of non-compliance, with the choice dictated by consideration of both safety hazards and impacts on consumers and need for power.55/

In light of the importance of the matter and the conflicting decisions and statements which have emerged from the AEC and the NRC over the years, the development of a clear Commission policy statement on safety philosophy would be highly desirable. Since the questions to be addressed would involve broad societal value judgments, interaction with the Congress and the President would be appropriate. One possible course would be for the Commission to develop a proposed statement, seek extensive public comment on it, adopt a final statement as a basis for Commission action and, while operating in accordance with the statement, submit it to the Congress for ratification or modification.

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55/ This authority to exercise "prosecutorial discretion" has never been articulated by the Commission. Corrective action in the face of an action by a licensee that is in violation of the regulations need not entail immediate plant shutdown absent some judgment on the part of the Commission that the hazards of construction or operation pending completion of enforcement hearings or licensee corrective action outweigh the impacts on ratepayers and energy supply. Confusion about this issue has led to a Staff practice of issuing operating licenses with minor items of noncompliance still outstanding on the theory that if the plant were already in operation the minor item would not be considered sufficiently serious to cause shutdown. This confuses enforcement discretion with discretion to issue a license that is not in full compliance. The former is a valid concept; the latter is a violation of the general rule of law that agencies are bound by their own regulations.

The following tables are based on:

- The food provisions of the Federal Food, Drug, and Cosmetic Act (contained in 21 U.S.C. 348 et seq)
- The drug provisions of the Federal Food, Drug, and Cosmetic Act (contained in 21 U.S.C. 348 et seq)
- The medical devices provisions of the Federal Food, Drug, and Cosmetic Act (contained in 21 U.S.C. 348 et seq)
- The cosmetic provisions of the Federal Food, Drug, and Cosmetic Act (contained in 21 U.S.C. 348 et seq)
- The Federal Meat Inspection Act (21 U.S.C. 601 et seq) and the Poultry Products Inspection Act (21 U.S.C. 451 et seq)
- The Federal Hazardous Substances Act (15 U.S.C. 1261 et seq)
- The Consumer Product Safety Act (15 U.S.C. 2051 et seq)
- The Occupational Safety and Health Act (29 U.S.C. 651 et seq)
- The Noise Control Act (42 U.S.C. 4901 et seq)
- The Toxic Substances Control Act (15 U.S.C. 2601 et seq)
- The Safe Drinking Water Act (42 U.S.C. 300 et seq)
- The Clean Air Act (42 U.S.C. 7401 et seq)
- The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq)

Statute (date of enactment and major amendments), Agency, and Jurisdiction	STATUTORY STANDARD FOR REGULATORY ACTION: Standard	Regulatory Decision or Action	AGENCY CONCERNS IN REGULATORY ACTION: Benefits
FOOD, DRUG, AND COSMETIC ACT (original statute enacted in 1906; major overhaul in 1938; major amendments in 1958, 1960 and 1968) o Administered by the Food and Drug Administration (FDA) o Regulates foods, drugs, cosmetics, medical devices, and substances therein FOOD PROVISIONS	Food Provisions: A. Raw agricultural commodities and their natural constituents (ex: vitamin C in orange juice): Food containing any poisonous or deleterious substances which "ordinarily" renders it injurious to health	A. Deeming a food to be adulterated if the poisonous or deleterious substance isn't "added".	A. Yes - Though the act neither authorizes nor precludes benefit consideration
	B. Contaminants (ex: aflatoxin in peanuts): 1. Substances considered "added" to food which are required or unavoidable by good manufacturing practice and which "may render" food injurious to health	1. Establishment of a tolerance level for an "added" poisonous or deleterious substance, or an "action level" for regulatory intervention. If this tolerance or action level is exceeded, the food is deemed adulterated	1. Yes - Considering unavoidability by good manufacturing practices involves economic and technologic feasibility
	2. Substances considered "added" to food which are avoidable by good manufacturing practice and "may render" the food injurious to health	2. Deeming a food to be adulterated for containing such a substance	2. No
	C. Direct Ingredients: 1. Direct Food Additive (ex: saccharin): a. "safe" for its intended use, functionally capable of accomplishing its intended effects, and	1. FDA approval of a direct food additive	a. Yes - Functionality
	b. Does not induce cancer in man, or through "appropriate" tests, in animals (Delaney Clause)		b. No
	2. Substances Generally Recognized as Safe (GRAS; ex: salt): Among qualified experts, substances generally recognized as safe for their intended uses	2. Exemption from the food additives provisions of the act (Delaney Clause does not apply)	2. Yes - Established usages
	3. Prior Sanctioned Substances (ex: nitrites in meat): Substances used historically with the sanction or approval of FDA and USDA before September 6, 1958.	3. Recognition of a prior sanction exemption from the food additives provisions of the act (Delaney Clause does not apply)	3. Yes - Though not explicitly authorized, FDA considers some benefits of use of the substance

AGENCY CONCERNS IN REGULATOR ACTION Risks	Routine, Rigorous Risk-Benefit Analysis?	Agency Emphasis on Mutagens, Carcinogens, or Teratogens?	Agency Discretion in Regulating Mutagens, Carcinogens, or Teratogens?	Procedure for Issuing Regulations	Use of Systematic Approaches to Information Gathering or Testing	Selected Other Regulatory Initiatives, Enforcement Efforts, or Devices
A. FDA employs Minimum Clinical Effect Levels to establish levels at which humans might be injured; courts require FDA to show a reasonable possibility of harm before acting, rather than a mere speculative risk	A. No	A. No	A. Yes	Informal rulemaking with notice and subsequent comment, except in certain circumstances, party adversely affected by agency action may request a hearing. These special circumstances arise in proceedings related to: • food standards • foods for special dietary uses • emergency permit controls • tolerances • food additive regulations • antibiotic animal drug certifications • new animal drug applications • color additive listings and certifications	• Advisory Committees • Agency testing and research • Monitoring of industries • Requests for data from manufacturers • Requirements of data submission by manufacturers seeking premarket approval of additives	• Labeling, nutritional information disclosure • GRAS list review • Inspections of industry • Seizure, condemnation, recall of adulterated or misbranded substances • Criminal penalties • In addition to rulemaking FDA simply may go to court over particular instances of food adulteration or misbranding
B. FDA must consider protection of public health and alternate modes of exposure to the substance	B. No	B. No	B. Yes			
	1. No	1. Yes	1. No			
a. Safety - FDA is required to consider consumption levels, cumulative effects, and expert approved safety factors b. Appropriate tests evidencing carcinogenicity in man or animal are dispositive						
2. GRAS regulations contain standards for evaluating food risks	2. No	2. Yes-It has been suggested that evidence of carcinogenicity would destroy any basis for "general recognition" of safety	2. Yes			
3. Risks or prior sanctioned substances evaluated similarly to those of added constituents - standard for regulatory action is whether substance "may render" food injurious to health	3. No	3. No	3. Yes			

Statute (s) and major amendment(s), Agency, and Jurisdiction	STATUTORY STANDARD — Standard	REGULATORY ACTION — Regulatory Decision or Action	AGENCY CONCERNS IN REGULATORY ACTION — Remarks
Food, Drug, and Cosmetic Act: Food Provisions (cont'd)	4. Color Additives (ex: Red No. 40):		
	a.1. Safe for its intended use and accomplishes its intended effect, or	a.1. Obtaining FDA approval of a color additive (including establishment of permitted levels of use)	4a. Functionality is the primary benefit considered
	a.2. Used and approved prior to 1960,	a.2. Obtaining temporary, provisional listing of color additive	
	b. But, if it induces cancer in man, or through "appropriate" tests, in animals	b. Revoking FDA approval of a color additive	4b. No-This "Delaney Clause" applies to all color additives (there is no GRAS or prior sanction exemption)
	D. "Indirect" Ingredients:		
	1. Indirect Food Additives (ex: acrylonitrile packaging materials) which "may reasonably be expected" to become a component of food	1. Regulation of indirect additives is similar to the regulation of intentional food additives (Delaney Clause, GRAS exemptions, prior sanctions apply)	1. See considerations for intentional food additives
	2. Animal Drug Residues (ex: sulfanomide) a. safe and efficacious in animals, b. residues are safe for humans, and c. no residues of any carcinogenic drug can be found in edible portions of animals by "approved" methods.	2. Obtaining FDA approval or sanction of animal drugs	2. Yes-The animal drug "Delaney Clause" is modified by a "DES proviso" that allows carcinogenic animal drugs to be used that don't adversely affect the animal recipients or leave residues detectable by "approved" methods
	3. Pesticide Residues (ex: heptachlor) - EPA has primary responsibility in this area		3. Yes - Delaney Clause doesn't apply to pesticide residues
	a. In raw foods if		a. Must show pesticides "useful" for the purpose for which tolerance is sought, and necessary to the food supply. Also, FDA must consider impact of its action on food prices and food supply to consumers.
	1. poisonous or deleterious pesticides, or pesticides not generally recognized as safe are used.	1. Tolerance level required	
	2. tolerance levels not necessary to protect public health	2. Exemption from tolerance level requirement	
	b. In processed foods if tolerance has been established, processing hasn't concentrated the pesticide, good manufacturing practices are followed	b. Pesticide deemed "safe" as an "additive"	b. In evaluating the extent to which "good manufacturing practice" has been followed in processing, some economic benefits may be considered.

AGENCY CONCERNS IN REGULATOR ACTION Risks	Routine, Rigorous Risk-Benefit Analysis?	Agency Emphasis on Mutagens, Carcinogens, or Teratogens?	Agency Discretion in Regulating Mutagens, Carcinogens, or Teratogens?	Procedure for Issuing Regulations	Use of Systematic Approaches to Gathering Information or Testing	Selected Other Regulatory Initiatives, Enforcement Efforts, or Devices
4a. Safety-FDA is required to consider probable consumption levels, cumulative effects, expert approved safety factors and the availability of certain analytic methods 4b. Appropriate tests evidencing carcinogenesis in man or animal are dispositive	4. No	4. Yes-Special advisory committees may be established when carcinogenicity is an issue in listing color additives	4. No			
1. FDA says "reasonably be expected to migrate" does not require that analytic methods must actually be able to detect residues in food, but that diffusion of a chemical within a substance creates a presumption of migration. Toxicologic data is examined, along with data from "food simulating" solvents. (Also, see considerations for intentional food additives)	1. No	1. Yes	1. Yes-for GRAS and prior sanctioned substances. No for others			
2. Safety - depends on probable consumption levels, cumulative effects on humans and animals, expert approved safety factors, and expected conformity of usage with labeling requirements Residues - FDA requires manufacturer to show extrapolated cancer risk of less than 1 in a million over a lifetime	2. Limited to determining safety and efficacy in animals. Not for determining safety of residues	2. Yes	2. Yes			
3. "Zero tolerances" are authorized, though carcinogens are not required to be banned	3. No	3. Yes - EPA guidelines on carcinogens exist	3. Yes			

Statute (date of enactment and major amendments); Agency, and Jurisdiction	STATUTORY STANDARD FOR REGULATORY ACTION: Standard	Regulatory Decision or Action	AGENCY CONCERNS IN REGULATORY ACTION: Benefits
DRUG PROVISIONS of the Food, Drug, and Cosmetic Act	A. Drugs which: 1) consist in whole or part of filthy, decomposed or putrid substances 2) are manufactured or processed under substandard conditions 3) will not have their purported effects 4) contain unsafe color additives 5) contain (or are) unsafe animal drugs.	A. Classification of a drug as adulterated	Yes-Evaluation of efficacy by FDA involves considering clinical, pharmacologic and therapeutic benefits
	B. Drugs which: 1) are labeled in a false or misleading manner 2) are not labeled as required by law 3) are dangerous when used in the manner suggested by the label 4) purport to be insulin or certain antibiotics but are not appropriately batch-certified.	B. Classification of a drug as misbranded	
	C. Drugs (except new animal drugs or animal feed containing a new animal drug) which: 1) are not generally recognized as safe and effective for the use and conditions stated on the label, or 2) have not extensively been used under the proposed conditions, or 3) have not been regulated and labeled similarly under the 1906 Food and Drug Act.	C. Classification of a drug as a new drug, requiring FDA approval of a new drug application (NDA)	
	D. Drugs which: 1) are habit-forming, or 2) require the supervision of a physician to be used safely.	D. Classification of a drug as a prescription, rather than over-the-counter, drug	
	E. New drugs which: 1) are not proven "safe" 2) are not shown by substantial evidence (based on expert investigation) to have their purported effect (efficacy) 3) are improperly labeled, or 4) are improperly processed or packaged	E. Disapproval of a new drug application; withdrawal of approval of new drug application (1-3 only)	
	F. New drugs which pose an imminent hazard to the public health	F. Immediate suspension of approval of new drug [illegible]	

AGENCY CONCERNS IN REGULATORY ACTION: Risks	Routine, Formal Risk-Benefit Analysis?	Agency Emphasis on Mutagens, Carcinogens, or Teratogens?	Agency Discretion in Regulating Mutagens, Carcinogens, or Teratogens	Procedure for Issuing Regulations	Use of Systematic Approaches to Gathering Information or Testing	Selected Other Regulatory Initiatives; Enforcement Efforts, or Devices
• Generally, determining "safety" involves evaluating health risks to humans or animals using data from laboratory, animal, and human experiments, as well as that from inadvertant or occupational exposure • Health risks from new drugs more closely evaluated than from drugs with established usages.	• Yes--New drugs are evaluated in risk-benefit terms. The risk of using the new drug is balanced against the benefits of use in setting "socially acceptable" levels of risk • Most drugs with established usage are not systematically subject to risk-benefit analysis; however, when sufficient evidence of adverse health effects from established drugs appears, risk-benefit analysis may be undertaken • Determination of adulteration or misbranding rarely involves risk-benefit analysis.	Evidence of carcinogenic, mutagenic, or teratogenic effects most important in evaluating new drugs rather than existing drugs, and in classifying drugs as either over-the-counter or prescription	Yes	Informal notice and comment rulemaking, except an aggrieved party may request a hearing in decisions involving: • prescription drug advertising • insulin regulations • antibiotic drug certifications • drugs liable to deterioration • strength, quality, and purity of drugs • new drug application requirements • habit-forming drugs	• Advisory committees for new drug applications • In-house review of new drug applications • Testing of existing drugs is not very frequently undertaken • Special consultants • Industry data heavily relied on • New drugs for chronic use are tested for two years in one or two species of rodents to determine potential human health effects.	• General review of existing data on over-the-counter drugs is currently being conducted • In addition to rulemaking FDA simply may go to court over particular instances of drug adulteration or misbranding • See "foods" for other enforcement devices

Incidence and risk of adverse reactions and significant side effects when used according to directions and potential for misuse are evaluated in classifying drugs as prescription or over-the-counter. Also, the seriousness of the disease being treated is important in this classification

Evidence obtained from "investigational" use of the new drug is evaluated in approving new drug applications. Evidence obtained subsequent to approval is emphasized in withdrawing approval of a new drug application

Statute (date of enactment or amendment) and Section	REGULATORY STANDARD FOR REGULATORY ACTION: Standard	Regulatory Decision or Action	AGENCY CONCERNS IN REGULATORY ACTION: Benefits
MEDICAL DEVICES PROVISIONS (enacted in 1976) of the Food, Drug, and Cosmetic Act	A. See drugs section on adulteration B. See drugs section on misbranding C. If "general controls" (including provisions on adulteration and misbranding, as well as certain other statutory provisions) are: 1. Sufficient to establish the safety and effectiveness of a device, or 2. Insufficient to ensure safety and effectiveness, but: o the device is not used to sustain life or of substantial importance in preventing impairment of health, and o It does not pose an "unreasonable" risk to human health	A. Deeming a device to be adulterated B. Deeming a device to be misbranded C. Classifying a device as "Class I", requiring only the application of "general controls"	Yes - Health benefits are evaluated in assessing the safety and efficacy of a medical device under the act.
	D. If "general controls" are insufficient to provide reasonable assurance that a device is safe and effective	D. Classifying a device as "Class II", requiring it to comply with FDA "performance standards" in addition to "general controls"	
	E. If both general controls and performance standards are insufficient to reasonably assure the safety and effectiveness of a device, and: o The device is used to sustain life or is of substantial importance in preventing impairment of health, or o it presents a potential "unreasonable" risk to human health	E. Classifying a device as "Class III", requiring FDA premarket approval, in addition to "general controls"	
	F. If: 1. There is no reasonable assurance that the device is safe or effective under the conditions stated in the label, or 2. "Good manufacturing practices" are not being followed in the production of the device, or 3. The labeling is false or misleading, or 4. The device does not comply with a performance standard and no insufficient reason exists for deviating from that standard, or 5. The manufacturer has inadequately maintained or provided access to records, or has failed to register as a manufacturer of a device	F. Revocation of premarket approval of a device; Refusal to grant premarket approval of a device (1→ only).	
	G. If other regulatory methods fail to provide reasonable assurances of safety and effectiveness of a device	G. Authorization to restrict the use, sale, or distribution of a medical device by written or oral "prescription" or otherwise as required by FDA	
	H. If a device presents "substantial deception" or "unreasonable and substantial risk of illness or injury", and labeling has not been undertaken that would sufficiently reduce substantial deception	H. Banning a device (can be done immediately)	

AGENCY CONCERNS IN REGULATORY ACTION Risks	Exemption, Rigorous Risk-Benefit Analysis?	Agency Emphasis on Workplace, Carcinogens, or Toxicology?	Agency Discretion in Regulating Hazards, Corridor-gens, or Toxicology?	Procedure for Issuing Regulations	Use of Systematic Information to Collection, or Testing	Selected Other Regulatory Initiatives, Enforcement Efforts, or Services
Agency frequently issued with devices with faulty design, improper functioning, contamination, and improper use - often risk arises after surgical implantation of a device. In vitro tests, tests on laboratory animals, and tests involving human investigational use of the device are evaluated.	Yes-Safety and efficacy are determined by balancing health risks and health benefits under the act.	No	Yes	• Classification of devices marketed before May 1976 as Class I, II, or III - notice and comment rulemaking (petitions for classification are also possible). New or unique devices automatically classified as Class III unless specifically reclassified by FDA. • Performance standards-FDA publishes an invitation to the public (includes contractors and other federal agencies) to develop a proposed standard. Existing federal standards may be proposed or FDA may propose its own standards. In all cases, notice and comment rulemaking follows • Requiring premarket approval of a device marketed before May, 1976-notice and comment rulemaking. No rulemaking required for new, unique Class III devices. • Banning a device-may be effective on publication of proposal in certain cases. Opportunity for an informal hearing required • Good manufacturing practice regulations - oral hearing required • Investigational use exemptions - may be granted without following rulemaking procedures. • Withdrawal of investigational use exemption - informal hearing required	• Advisory committees for classifying devices, and for review of performance standards, good manufacturing practice regulations and orders, premarket approval applications. • Investigations for establishing the effectiveness of a device may be undertaken. • Reports and records must be maintained by manufacturers. • Investigational use exemptions from premarket approval procedures.	• Manufacturer's warnings of device defects • Refund of purchase price, repair, replacement of a defective device • "Good manufacturing practice" rules • Attempts to regulate device "users" (usually health care professionals) being studied • High priority given to regulating cardiac monitoring systems, defibrillators (used to halt irregular hearing of the heart), devices used to restore breathing in emergencies, and other life supporting devices. • FDA authorized to exempt devices from strict regulation for investigational purposes (FDA regulation not yet effective) • Labeling (e.g. IUD's, hearing aids) • Voluntary or FDA requested recalls used frequently to remove violative products from the market

Statute (date of enactment and major amendments); Agency, and Jurisdiction	STATUTORY STANDARD FOR REGULATORY ACTION: Standard	STATUTORY STANDARD FOR REGULATORY ACTION: Regulatory Decision or Action	AGENCY CONCERNS IN REGULATORY ACTION: Benefits?
COSMETIC PROVISIONS of the Food, Drug, and Cosmetic Act	A. If a cosmetic: 1) bears or contains any poisonous or deleterious substance which may render it injurious to health under the conditions prescribed in the label, or under such conditions of use as are customary or usual, or 2) consists in whole or in part of any filthy, putrid, or decomposed substance, or 3) has been prepared, packed, or held under insanitary conditions or 4) has a container composed of any poisonous or deleterious substance which may render the contents injurious to health, or 5) contains an unsafe color additive (as defined in the act), except for hair dyes.	Deeming a cosmetic to be adulterated	Very limited - FDA considers most cosmetics to have no significant health benefits
	B. If a cosmetic is labeled in a false or misleading manner	Deeming a cosmetic to be misbranding	
FEDERAL MEAT INSPECTION ACT (enacted in 1906, major amendments in 1967 and 1970); POULTRY PRODUCTS INSPECTION ACT (enacted in 1957, amended most recently in 1968) • Administered by U.S. Department of Agriculture (USDA) • Regulate red meat and red meat food products, poultry and poultry products • Jurisdictional question concerning control of food additives and pesticide residues in meat and poultry addressed by memorandum of understanding between USDA, FDA and EPA, respectively. For food additives FDA determines safety and USDA decides whether it can be used in meat; for pesticides EPA sets tolerances with which USDA usually agrees. In both cases, however, USDA can set stricter standards than FDA or EPA	If any meat or poultry product: • Contains poisonous or deleterious substances • Contains any pesticide, chemical, food additive, or color additive that is unsafe under the Food, Drug, and Cosmetic Act • Has been prepared, packed or held under unsanitary conditions • Is statutorily prescribed or deemed unfit for human consumption	Deeming meat or poultry to be adulterated	Yes - USDA officials indicate that some benefits are evaluated in determining an "acceptable risk"

AGENCY CONCERNS IN REGULATORY ACTION Risks	Routine, Rigorous Risk-Benefit Analysis?	Agency Emphasis on Mutagens, Carcinogens, Teratogens?	Agency Discretion in Regulating Mutagens, Carcinogens, or Teratogens?	Procedure for Issuing Regulations	Use of Systematic Approaches to Gathering, or Testing	Selected Other Regulatory Initiatives, Enforcement Efforts, or Devices
• Due to FDA's opinion that cosmetics have no significant health benefits, it is much less tolerant of any potential for injury from cosmetics • FDA is usually confronted with localized, short-term, allergy-related responses to cosmetics; long-term risks are largely unstudied.	No	No, but FDA encourages manufacturers to conduct short term mutagenesis tests	Yes	• Informal notice and comment rulemaking	FDA is not authorized to require premarket testing of cosmetics, or to require manufacturers to prove the safety of their products before marketing them. Consequently, FDA often relies on voluntary testing programs by manufacturers.	• Ingredient labels • Warning labels (e.g., in hair dyes) • Voluntary registration of products • FDA limited to post-marketing enforcement efforts (For remedies once a cosmetic is deemed adulterated or misbranded, see "foods" section)
Regulatory efforts are directed primarily at risks of microbial and chemical adulteration, and risk of disease	No	No, except in fulfilling its responsibilities to enforce animal drug, food additive, and pesticide residue regulations of FDA and EPA	Yes, except residues above FDA or EPA "tolerances" must be reported to these agencies	Notice and comment rulemaking generally	• Inspections administered by the Food Safety and Quality Service 1. Slaughter operation inspections -reliance primarily on visual inspection 2. Processing inspections -emphasis on supervision rather than individual product inspection. 3. Chemical residue surveillance - USDA conducts continuous "blind" monitoring system to analyze samples for approximately 60 different types of chemicals and pesticides regulated by FDA and EPA.	• Inspected meat and poultry may be detained, seized or condemned. Permission to operate a manufacturing or processing plant may be withheld until sanitary requirements are met. Facility may be permanently shut down, though this rarely occurs. • State inspection activities partially funded by federal government • Technical assistance available to states

Statute (date of enactment and major amendments), Agency, and Jurisdiction	STATUTORY STANDARD FOR REGULATORY ACTION: Standard	STATUTORY STANDARD FOR REGULATORY ACTION: Regulatory Decision or Action	AGENCY CONCERNS IN REGULATORY ACTION: Benefits
FEDERAL HAZARDOUS SUBSTANCES ACT (enacted in 1960, major amendments in 1966 and 1969) • Administered by the Consumer Product Safety Commission • Regulates consumer product hazards except pesticides, tobacco products, foods, drugs, cosmetics, portable fuels, and certain nuclear materials	A. Toxic, corrosive, flammable, combustible, or irritating substances that may cause "substantial" illness from "customary or reasonably foreseeable" use	A. Labeling hazards, or if that is inadequate, then banning hazards	Yes - Courts have said Commission must consider the effect of the regulation on manufacturers and consumers
	B. Toys or articles intended for use by children presenting an "electrical, mechanical, or thermal hazard," or which bear or contain hazardous substances	B. Banning such hazards	
CONSUMER PRODUCT SAFETY ACT (enacted in 1972, major amendments in 1976, 1977 and 1978) • Administered by the Consumer Product Safety Commission • Regulates consumer product hazards except firearms, motor vehicles, tobacco products, aircraft, boats, pesticides, foods, drugs and cosmetics • Commission must defer to the regulatory authority of other agencies under the Clean Air Act, the Atomic Energy Act, and the Occupational Safety and Health Act.	A. Reasonably necessary to prevent or reduce an unreasonable risk of injury.	A. Substantive safety standards regulating performance (preferably) composition and design of consumer products; banning or labeling a product.	Yes - Legislative history indicates CPSC should consider the effect of a regulation on the cost, utility, and availability of a product to consumers
	B. Imminent and unreasonable risk of death, serious illness, or severe personal injury.	B. Seeking an injunction against an imminent hazard.	
	C. Substantial risk of injury, or failure to comply with a safety rule.	C. Regulating substantial product "hazards".	

AGENCY CONCERNS IN REGULATORY ACTION Risks	Routine, Rigorous Risk-Benefit Analysis?	Agency Emphasis on Mutagens, Carcinogens, or Teratogens?	Agency Discretion in Regulating Mutagens, Carcinogens, or Teratogens?	Procedure for Issuing Regulations	Use of Systematic Approaches to Information Gathering or Testing	Selected Other Regulatory Initiatives, Enforcement Efforts, or Devices
A. Courts have said no precise "risk count" is necessary, but Commission should consider probability and severity of injury B. Substantial injury standard requires Commission to focus on non-trivial risks	No	Yes-An interim policy on the generic regulation of carcinogens in consumer products has been proposed. Court has enjoined its implementation due to commission's failure to comply with proper rulemaking procedures.	Yes	• Commission uses the "formal" rulemaking procedures provided for in the Food, Drug, and Cosmetic Act for regulating hazardous substances. Toys, however, may be regulated using informal notice and comment rulemaking procedures.	• Inspections of manufacturers	• Seizure of misbranded substances • Repurchase orders mandatory after banning a substance • Criminal penalties
"Reasonably foreseeable exposures" to particular hazards are estimated and given great weight. Risk of injury has been found to be crucial to Commission's actions.	No	Yes-An interim policy on the generic regulation of carcinogens in consumer products has been published. Court has enjoined its implementation due to Commission's failure to comply with proper rulemaking procedures	Yes	• Notice soliciting offer to develop a standard. Unless an existing federal standard is adequate to address the particular hazard, the Commission must accept an offer or develop one of its own. This becomes the proposed rule, and informal notice and comment rulemaking follow, with the opportunity for interested persons to make oral presentations. • Petitions to develop or amend rules may be submitted by interested persons.	• National Injury Information Clearinghouse: o hot line • death certificate collection • National Electronic Injury Surveillance System (NEISS) -monitors emergency room admissions and provides data for Consumer Product Hazard Index • Product Safety Advisory Council-recommends standards • Investigative hearings • Manufacturer notification of substantial product hazards • Recordkeeping by manufacturers	• Private damage suits • Inspections • Civil, criminal penalites • Recall, repair, replacement of risky products. Also, refund of purchase price.

Statute (date of enactment and major amendments), Agency, and Jurisdiction	STATUTORY STANDARD FOR REGULATORY ACTION: Standard	STATUTORY STANDARD FOR REGULATORY ACTION: Regulatory Decision or Action	AGENCY CONCERNS IN REGULATORY ACTION: Benefits
OCCUPATIONAL SAFETY AND HEALTH ACT (enacted in 1970) • Administered by the Occupational Safety and Health Administration • Regulates hazards in the workplace. Excludes authority over other federal agencies, or where those agencies exercise prior authority	A. Furnish employees a place of employment "free from recognized hazards" likely to cause death or serious harm.	A. Employer's duty under the "general duty" clause of the act.	Yes - Economic and technologic feasibility involved in determining "recognized" hazards. Courts say when viability of employer threatened, general duty standard is infeasible.
	B. "Grave danger" from exposure to toxic or physically harmful substances, or from new hazards.	B. Issuing an emergency temporary standard	Yes - Economic and market factors may enter into the agency's decision to issue an emergency standard.
	C. "Material impairment" of health of employees	C. Issuing a permanent standard	Yes - The statute specifically says permanent standards must be "feasible." • Economic infeasibility - involves massive "industry wide" disruption to challenge most standards; enforcement of some "minor" standards has been challenged successfully for lesser economic disruptions. • Technologic infeasibility - As statute is "technology forcing," such challenges unlikely to succeed, though theoretical limits on technologic feasibility exist.
NOISE CONTROL ACT (enacted in 1972) • Administered by EPA • Regulates noise and noise sources; EPA is also supposed to coordinate noise control activities with other agencies • Primary responsibility for aircraft noise control is in the Federal Aviation Administration	Protect the public health and welfare	Issuing noise control standards	Yes - Statute explicitly requires EPA to consider the costs and technology of compliance

AGENCY CONCERNS IN REGULATORY ACTION: Risks	Routine, Rigorous Risk-Benefit Analysis?	Agency Emphasis on Mutagens, Carcinogens, or Teratogens?	Agency Discretion in Regulating Mutagens, Carcinogens, or Teratogens?	Procedure for Issuing Regulations	Use of Systematic Approaches to Gathering Information or Testing	Selected Other Regulatory Initiatives, Enforcement Efforts, or Devices
Courts have said that practices other than "freakish occurrences" leading to serious injury may be dealt with under the general duty clause. Regulates risks that "reasonably" are matters of general knowledge. Under this standard, courts have said that prophylactic regulation of carcinogens is still possible: Need not wait until actual harm occurs, but harm must be serious and preferably documented by epidemiologic data. Under proposed rules regulating occupational carcinogens: • Epidemiologic data heavily weighed • Animal tests, especially if duplicated, are acceptable • "Short term" tests are given supportive value • Agency considers there to be no safe "threshold" level for exposure to carcinogens. For non-carcinogenic toxic substances, agency considers threshold levels of toxicity to exist. Epidemiologic and animal test data are weighed.	No	Yes—Generic rules on occupational carcinogens have been proposed.	Yes	• Emergency temporary standards effective on publication • Permanent standards-informal notice and comment rulemaking. Informal public hearing available on request. • Many pre-existing federal standards adopted by reference.	• Use of advisory committees is optional in issuing standards • National Institute of Occupational Safety (NIOSH) conducts research and testing, and recommends standards • "Fact-finding" hearings sometimes held. • Recordkeeping by employers	• On-site inspections of employers • Civil and criminal penalties • Agency sometimes issues enforcement "guidelines" for employers
• Statute singles out certain noise sources for regulation • EPA considers the physiologic, psychologic, and "quality of life" effects of noise	Yes	No	Yes	Informal notice and comment rulemaking. Public hearings normally held.	• Advisory committees • Recordkeeping by manufacturers • Funding for research activities	• Labeling "noisy" products • Designating certain "low noise" products for preferential purchase by the government; development of low noise products • Citizen suits • Civil, criminal penalties

Statute (date of enactment and major amendments), Agency, and Jurisdiction	STATUTORY STANDARD FOR REGULATORY ACTION: Standard	STATUTORY STANDARD FOR REGULATORY ACTION: Regulatory Decision or Action	AGENCY CONCERNS IN REGULATORY ACTION: Benefits?
TOXIC SUBSTANCES CONTROL ACT (enacted in 1976) • Administered by EPA • Regulates toxic substances, not including firearms, pesticides, special nuclear material, tobacco products, foods, drugs, cosmetics • EPA has complete descretion to use TSCA instead of other EPA administered laws; although EPA can exhort other agencies to regulate a particular substance, only in certain circumstances can it regulate substances within the jurisdiction of these other agencies	A. "Unreasonable risk" to health or the environment B. Imminent and unreasonable risk of serious or widespread injury	A. Limiting, banning, or labeling chemical hazards B. Immediate ban of a chemical hazard	Yes - statute and legislative history indicate that EPA should consider benefits, available substitutes, economic and technologic consequences of regulation. Also, approach least burdensome to industry must be used.
SAFE DRINKING WATER ACT (enacted in 1974; amended 1977) • Administered by EPA • Regulates drinking water and substances therein	A. Standards which shall protect health to the extent feasible B. Levels of contaminants which will produce no known or anticipated adverse health effects with an adequate margin of safety C. Standards which shall be as close to the recommended maximum contaminant levels as is feasible; or which shall specify water treatment techniques that prevent known or anticipated adverse health effects to the extent feasible D. Standards regulating the odor or appearance of drinking water or otherwise necessary to protect the public welfare	A. Interim primary drinking water regulations (maximum contaminant levels or treatment techniques) B. Recommended maximum contaminant levels (MCL's) (unenforceable health goals) C. Revised primary drinking water regulations (to be issued after interim primary regulations and National Academy of Sciences report) D. Secondary drinking water regulations (not federally enforceable)	Yes - regulations are established based upon economic and technologic feasibility; also, health benefits of contaminants present in water are evaluated

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AGENCY CONCERNS IN REGULATORY ACTION: Risks	Routine, Rigorous Risk-Benefit Analysis?	Agency Emphasis on Mutagens, Carcinogens, or Teratogens?	Agency Discretion in Regulating Mutagens, Carcinogens, or Teratogens?	Procedure for Issuing Regulations	Use of Systematic Approaches to Information Gathering or Testing	Selected Other Regulatory Initiatives, Enforcement Efforts, or Devices
Act singles out carcinogens, mutagens, and teratogens for priority attention by EPA EPA has indicated its intention to focus on high toxicity chemicals producing irreversible or slowly reversible and debilitating effects	Possibly yes, but act is relatively new	Yes - EPA emphasizes the testing and regulation of carcinogens, mutagens, and teratogens	Yes, except act requires "appropriate action" when evidence is obtained	• Informal notice and comment rulemaking, with the opportunity for aggrieved parties to appear in person before a hearing examiner and cross-examine witnesses • Citizens may petition EPA to amend, issue, or revoke a rule	• Premarket notification given to EPA by manufacturers of all new chemicals. • Testing rules for manufacturers • Interagency Testing Committee recommends chemicals for testing • Reporting requirements for manufacturers • Funding for scientific research • Inspection of manufacturers	• Seizure of non-complying substances • Citizen suits • Civil and criminal penalties
EPA evaluates potential "human risk" rather than determining "safety". Animal test data may be used in this evaluation, and extrapolations made from high doses to low doses. Epidemiologic data is also considered. "Threshold levels" for long term non-carcinogenic chemicals are assumed to exist, and are set at levels producing "no observed adverse effect."	No	Yes - for carcinogens EPA assumes ther are no threshold "safe" levels of exposure	Yes	• Informal notice and comment rulemaking	• National Drinking Water Advisory Council • Recordkeeping and reporting by water suppliers • Inspections of water suppliers are authorized • Grants for studying the technology for treating drinking water, and the health effects of drinking water	• States have primary enforcement responsibility • Citizen suits permissible • Notification to the public of violations

Statute (date of enactment and major amendments), Agency, and Jurisdiction	STATUTORY STANDARD FOR REGULATORY ACTION: Standard	STATUTORY STANDARD FOR REGULATORY ACTION: Regulatory Decision or Action	AGENCY CONSIDERS IN REGULATORY ACTION: Benefits
CLEAN AIR ACT (enacted in 1963, amended most recently in 1977) • Administered by EPA; states have primary responsibility to develop and enforce state implementation plans to comply with statutory standards and goals • Regulates air pollutants and their sources	A. Pollutants which cause or contribute to air pollution and which: 1. May reasonably be anticipated to endanger the public health or welfare	1. Designation of a substance as a "criteria" pollutant, leading to the establishment of a primary and secondary ambient air standard. Also governs mobile sources of pollution (e.g., motor vehicles, aircraft) requiring an emission standard, regulation of fuels and fuel additives, establishment of "standards of performance" for stationary sources of air pollution.	Yes - While ambient air standards are strictly "health-based," the act frequently allows for the consideration of economic and technologic benefits (e.g., costs and technology of air pollution control)
	2. May reasonably be anticipated to result in an increase in serious irreversible, or incapacitating reversible illness	2. Designation of a substance as a hazardous pollutant (requiring a stricter standard of control)	
	B. Standards which are: 1. Requisite to protect the public health with an adequate margin of safety	1. Establishment of primary ambient air standards	
	2. Requisite to protect the public welfare from any known or anticipated adverse effects	1. Establishment of secondary ambient air standards	
FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (enacted in 1947, amended by the Federal Environmental Pesticides Control Act in 1972 and the Federal Pesticide Act in 1978) • Administered by EPA • Regulates pesticides; tolerances in foods established in cooperation with the Food and Drug Administration under the Food, Drug, and Cosmetic Act	Unreasonable adverse effects on the environment	1. Considering application for EPA approval (registration) of a pesticide 2. Notice of intent to cancel registration 3. Cancellation of registration 4. Immediate suspension of registration (imminent hazards) 5. Considering whether to allow general or restricted use of a pesticide	Yes-Statute requires EPA to consider the economic, social, and environmental benefits of using the pesticide. EPA emphasizes agricultural and consumer benefits, rather than benefits to manufacturers

AGENCY CONCERNS IN REGULATOR ACTION Risks	Routine, Rigorous Risk-Benefit Analysis?	Agency Emphasis on Mutagens, Carcinogens, or Teratogens?	Agency Discretion in Regulating Mutagens, Carcinogens, or Teratogens?	Procedure for Issuing Regulations	Use of Systematic Approaches to Gathering Information or Testing	Selected Other Regulatory Initiatives, Enforcement Efforts, or Devices
Health, environmental, economic risks are considered. Risks to humans, animals, vegetation, and "public welfare" are weighed (including an evaluation of aesthetic and structural damage caused by air pollution)	No	Carcinogen policy being developed	Yes	• Most rules can be issued after notice and comment rulemaking with an opportunity for oral presentation. • Approving state implementation plans - if state holds appropriate hearings (require an opportunity for "effective" presentation-may include a requirement for oral presentation and cross-examination) EPA need not hold an additional hearing on the state implementation plan	• Scientific Review Committee reviews criteria pollutants and ambient air standards • National Academy of Sciences reviews auto emission standards and ambient air standards • National Commission on Air Quality-studies the feasibility and alternatives to protecting and enhancing the air quality; also examines the economic, technologic, and environmental consequences of air pollution control • Advisory committees can be used	• Transportation control plans (e.g., car pools) • Non-degradation-air cleaner than ambient air standards is not allowed to deteriorate "significantly" (specified numerically) • Non-attainment plans - allow for continued industrial growth for a limited time in areas dirtier than the ambient air standards if states use "reasonable" measures to establish "reasonable" progress in meeting ambient air standards as quickly as "practicable"
• EPA must consider the economic, social, and environmental costs of using the pesticide • EPA has established a "rebuttable presumption" against registering an oncogenic pesticide-that is, such a pesticide is considered unsafe unless proven otherwise • EPA focuses on three types of risks: a. Emergency b. Acute Toxicity c. Chronic Toxicity • For "imminent hazards" EPA must find a "substantial likelihood" of serious harm during administrative proceedings • Oncogenicity may be based upon findings in test animals	No	Yes-Agency guidelines on cancer causing substances have been issued. Cancer Assessment Group evaluates chronic toxicity risks	Yes	• Notice and comment rulemaking generally, except USDA and a Scientific Advisory Panel must be given an opportunity to scrutinize and comment on regulations	• Recordkeeping by manufacturers • Manufacturer notification of certain product hazards • Registration of pesticide manufacturers • Inspection of manufacturers • Scientific Advisory Panels review regulations	• Seizure of mislabeled or unregistered pesticides • Civil, criminal penalties • Orders involving penalties and registration may be issued after a formal adjudicatory hearing (if requested), except: a. Orders suspending the registration of a pesticide-"expedited" hearing held b. Emergency orders-may be effective immediately, followed by expedited hearings • "Stop-sale" orders may be issued to prevent continued distribution of violative products.