

LECTURE NOTES: EMGT 234

AN ANALYSIS OF THE DE MINIMIS STRATEGY FOR RISK MANAGEMENT

SOURCE:

Jeryl Mumpower, Risk Analysis, Vol. 6, No. 4,
pp. 437-446, 1986

1. INTRODUCTION

De minimis risk level:

Popular in federal agencies to decide whether hazard poses a potentially significant risk to public.

Definition: De minimis risk level

I: Risk higher than de minimis threshold



further analysis, possibly regulation

II: Risk lower than de minimis threshold



Risk dismissed. Even when Risk > 0

De Minimis Approach calls for a threshold that is:

- Precise
- Numeric
- Constant across types of risk

Argument:

Contributes to effective Risk Management, because it eliminates the trivially low risks and allows focus on real risk issues.

2. THE CONCEPT OF DE MINIMIS RISK

Rational:

Ignore those risks that are so unlike they are ordinarily ignored.

Example:

Being struck by a meteorite. Non-zero Risk, but ignored.

Origin: Common Law

De minimis non curat lex =
"The law does not concern itself with trifles"

Comar (1979) first to use it in Risk Management context.

Proposed Risk Threshold: 10^{-5} risk of death per person year. Ignore is less than Threshold, unless no benefit to activity or easily reducible.

Grounded in Cost-Benefit analysis. Argument:
Risks so low \longrightarrow costs of reduction outweigh the benefits.

De minimis argument: Applied to the probability of a severe negative consequence, most commonly mortality.

De minimis question:

At what probability level, if any,
a risk of mortality can reasonably be ignored.

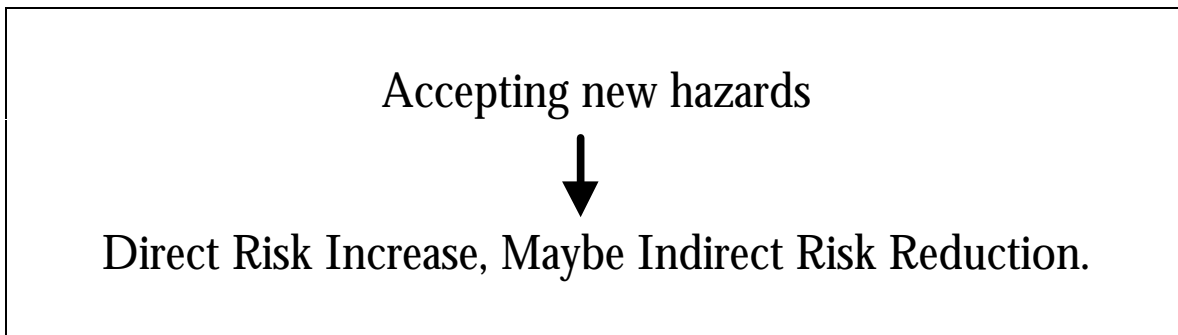
3. A DISTINCTION BETWEEN OLD VS. NEW RISKS

Old risk : Those existing at present.

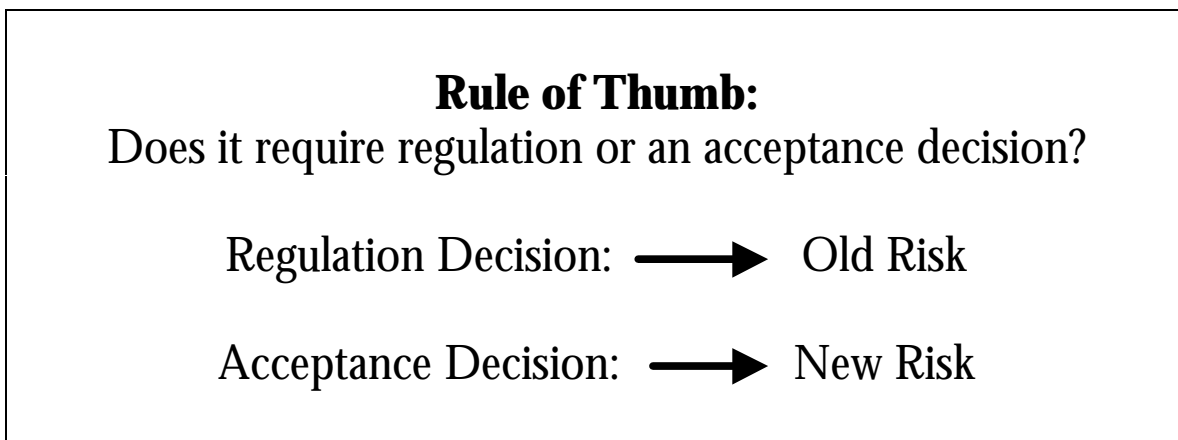
Decision : To take regulatory actions or not.

New risk : Resulting from introducing new hazardous products, substances, processes, or activities.

Decision : To accept such new risks or not



Distinction sometimes fuzzy: e.g. new information leads to drastically revised estimates of the level of risk associated with an existing hazard.



4. APPLYING THE DE MINIMIS-STRATEGY TO OLD RISKS

Assumption 1:

Pool of hazards has an overall level of risk such that there is motivation to reduce it. The overall level can be lowered by reducing or eliminating the risk associated with any existing hazard.

Accept Assumption 1 → de minimis strategy reasonable.

At worst : It does no harm.

At best : Useful tool for easing risk management process.

4.1 Based on Initial Risk Level

1. Consider consequences when implementing de minimis rule if risk management decisions were based solely on risk level.
2. Assume level of risk can be estimated and expressed in annual probability of mortality given you are exposed and that there are many more low-level risks than high-level ones.

Claim:

Even if no consideration is given to any other factors, such as:

- Cost,
- Size of Exposed Population,

the de minimis approach is harmless. **Why?**

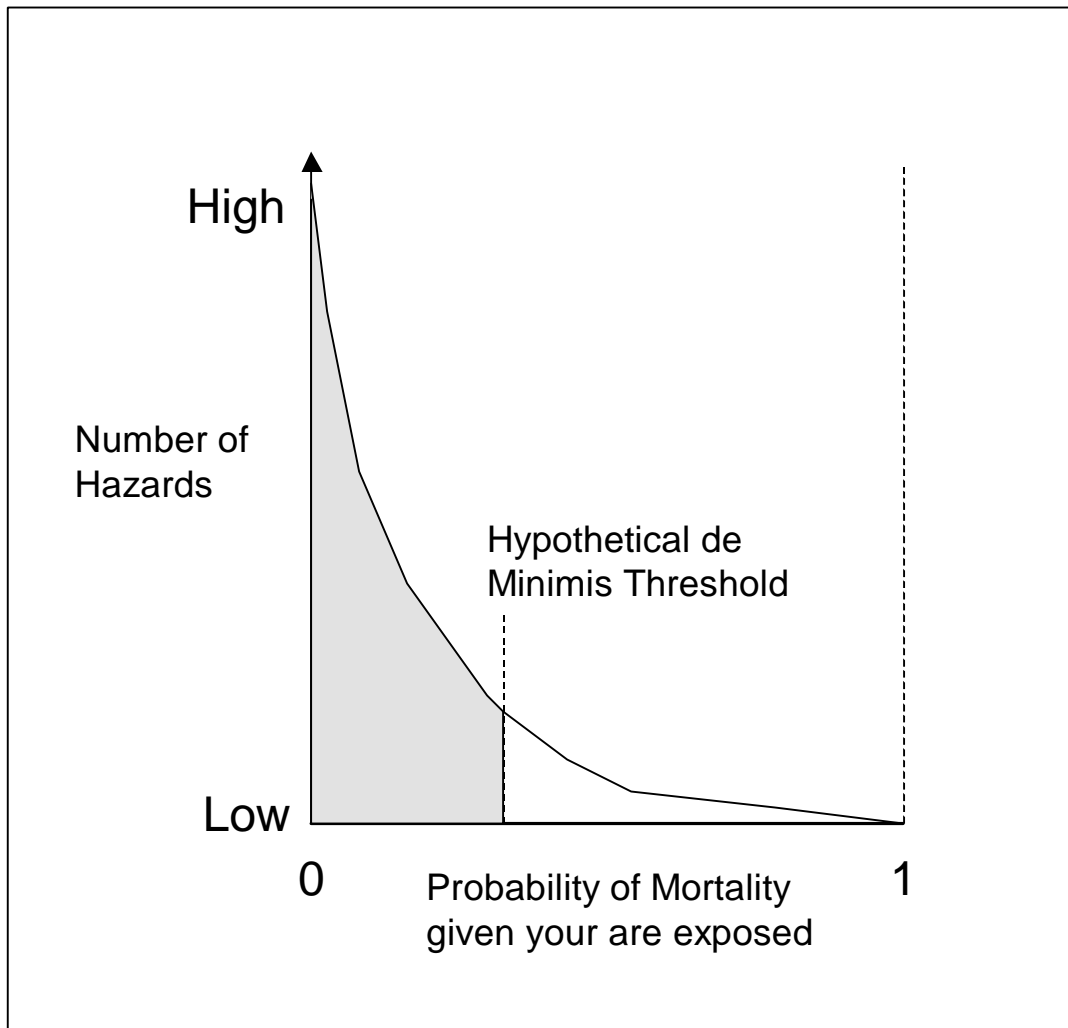


Figure 1. A hypothetical de Minimis Risk Level

- It would always be preferable to eliminate a risk larger than the de minimis level than one smaller than that level.
- Above statement is true, if in the unlikely case that all risks above the de minimis level are removed, the de minimis level can be reset to a lower one.

4.2. Initial Risk Level vs. Risk Reduction Potential

Initial risk level not a perfect indicator
of risk reduction potential.

- Not every risk can be totally eliminated.
- Some risk are more *easily* reduced than others
- Initial risk level defines an upper bound for risk reduction

Claim:

Penalties associated with establishing a de minimis threshold are small. **Why?**

Assumptions:

- Set De Minimis Threshold at 10^{-7}
- All risks below threshold can be completely removed.
- All risks above threshold are of 10^{-5} and can only be reduced by 10%

Note:

- Reducing a hazard with a risk of 10^{-5} by 1% is equivalent with eliminating a risk of 10^{-7} .
- Reducing a risk of 10^{-5} by 10 % is equivalent to reducing 10 risks of 10^{-7} .

Conclusion:

If for example, the ratio of (1) number of risks below threshold to (2) number of risks above threshold is less than 10:1, a higher level of risk reduction would be achieved by reducing the risks of 10^{-5} by 10% than eliminating all risk below the threshold.

4.3. Population Size

- Publics Perception of Annual Risk depends on the number of people exposed.
- A de minimis risk level, defined in terms of probability of mortality per exposed individuals, does not take into account the total number of people exposed and therefore does not take into account the annual frequency of mortality.

Example:

Suppose de minimis threshold at 10^{-6}

A 10^{-6} annual risk affecting 2.3×10^8 people
(= U.S. Population)



E[deaths per year] = 230 people
(=Should this be ignored?)

First Alternative:

Define de minimis levels in terms of the annual frequency of mortality

Problem:

10^{-6} Risk for 2.3×10^8 people (US Population)=
 10^{-2} Risk for 2.3×10^4 people (Small Town)

Which one would you prefer to address first?

"Inevitable tension between Efficiency and Equity"
i.e. between saving lives and protecting individuals.

- Achieving Efficiency and Achieving Equity are both objectives for risk management decision making.
- Achieving Efficiency and Achieving Equity typically are conflicting objectives.
- Society generally wishes both to save as many lives as possible and be fair- in the process at the same time.
- Rarely can both goals be fully achieved.

Second Alternative:

Establishing two de minimis levels:

1. Based on the level of risk per exposed individuals,
2. Based on annual frequency of mortality.

Example:

Risk exceeds de minimis threshold if:

- (A) it exceeds threshold of 10^{-6} per exposed individuals,
- or
- (B) it is expected to result in more than 100 fatalities annually.

Note:

Risk per exposed individual and US population provides upper bound on threshold for annual frequency of mortality and vice versa.

{ De Minimis Level of Risk per Exposed Individual
{ Number of Exposed Individuals



Upper Bound on Annual Frequency of Mortality

{ De Minimis Level of Annual Frequency of Mortality
{ Number of Exposed Individuals



Upper Bound on Risk per Exposed Individual

Example:

{ De Minimis Level of 10^{-6} per Exposed Individual
{ $2.3 \cdot 10^8$ Exposed Individuals (= US Population)



De Minimis level on Annual Frequency of Mortality
 ≤ 230

Dual levels addresses both efficiency objective and equity objective. However, trade-offs between objectives are not eliminated, but are delayed until later stages of the process.

Risk Perception issue with dual de minimis rule.

- (a) Risk per exposed individual will always be small (in order of e.g. 10^{-2}) and definitely smaller than 1
- (b) Annual Frequency of mortality involves typically number larger than one, sometimes quite large.

Example:

- (a) "Annual Frequency of Mortality of 230 people"
- (b) "A one-in-the million risk of death for each US citizen."

Psychologically and **Politically** above statements are typically not equivalent.

4.3. Trading Off Cost vs. Risk Reduction

Risk management Process involves

Making Decisions trading off economic and social costs of risk reduction measures against the benefits of reducing risk.

$$\left\{ \begin{array}{l} \text{Benefits} \geq \text{Costs} \Rightarrow \text{Enact Risk Reduction Measure} \\ \text{Benefits} < \text{Costs} \Rightarrow \text{Disregard Risk Reduction Measure} \end{array} \right.$$

Approach: Enact Risk Reduction Measures in Rank Order of cost effectiveness, until:

1. the benefits from additional risk reduction are exceeded by costs, or
2. attempts to further reduce risks back fire and produce higher risk levels instead

Conclusion:

- If **full and accurate** information about costs and benefits were available, the entire notion of a de minimis risk level would be obsolete.

Claim:

With Incomplete information about Risks and Costs the wisdom of the de minimis approach depends on the relationship between risk and risk reduction per unit investment. **Why?**

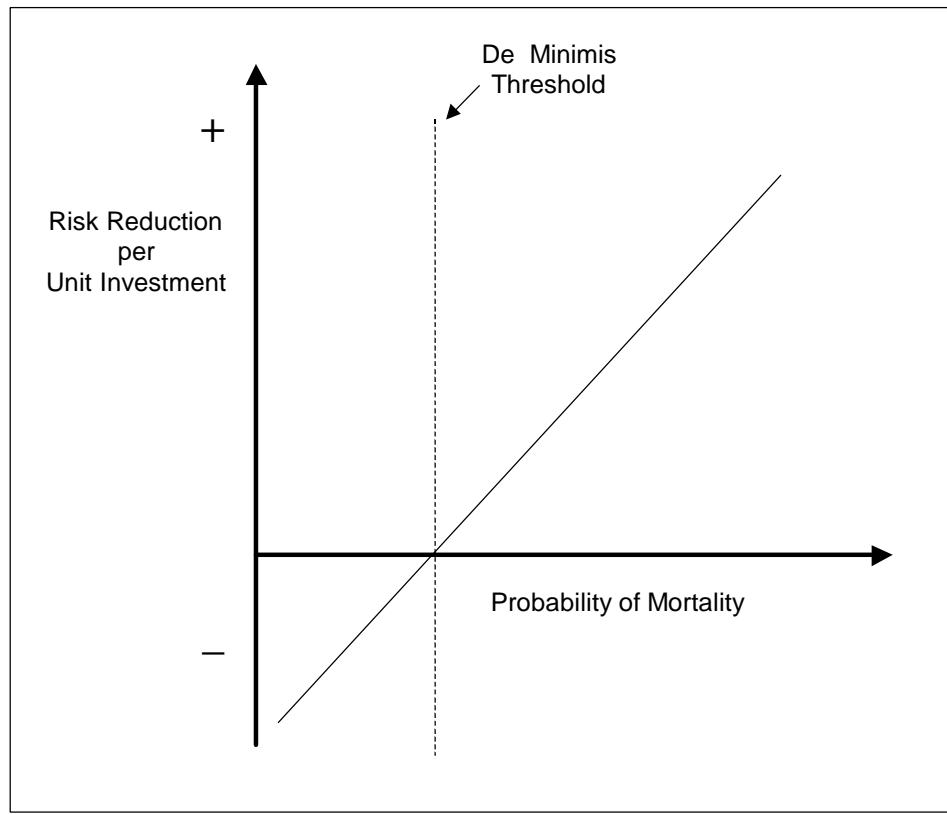


Figure 2A. Hypothetical Relationship between risk level and cost-effectiveness of risk reduction.

Does the de Minimis Approach make sense in the figure above?

Conclusion:

The de minimis strategy eliminates from consideration those risk which offer lowest rate of return.

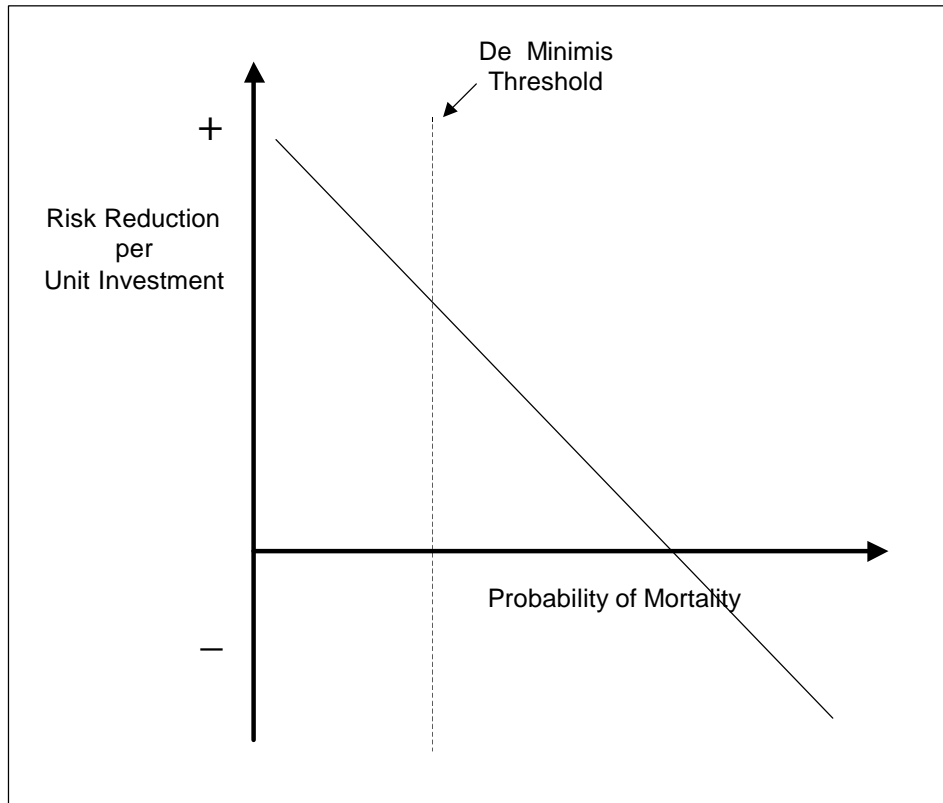


Figure 2B. Hypothetical Relationship between risk level and cost-effectiveness of risk reduction.

Does the de Minimis Approach make sense in the figure above?

Conclusion:

Figure 2B The de minimis strategy would not work when a negative correlation exist between risk level and risk reduction per unit investment.

Do you think that large risks are typically more expensive to reduce?

However:

- Little evidence to no evidence to support relationship in Fig 2a. or Fig 2b.
- There may be little correlation to no correlation between risk levels and costs of risk reduction.

Does the de minimis approach make sense in the latter case?

Assumption:

There are many more risks with a high cost of risk reduction than with a low cost of risk reduction.

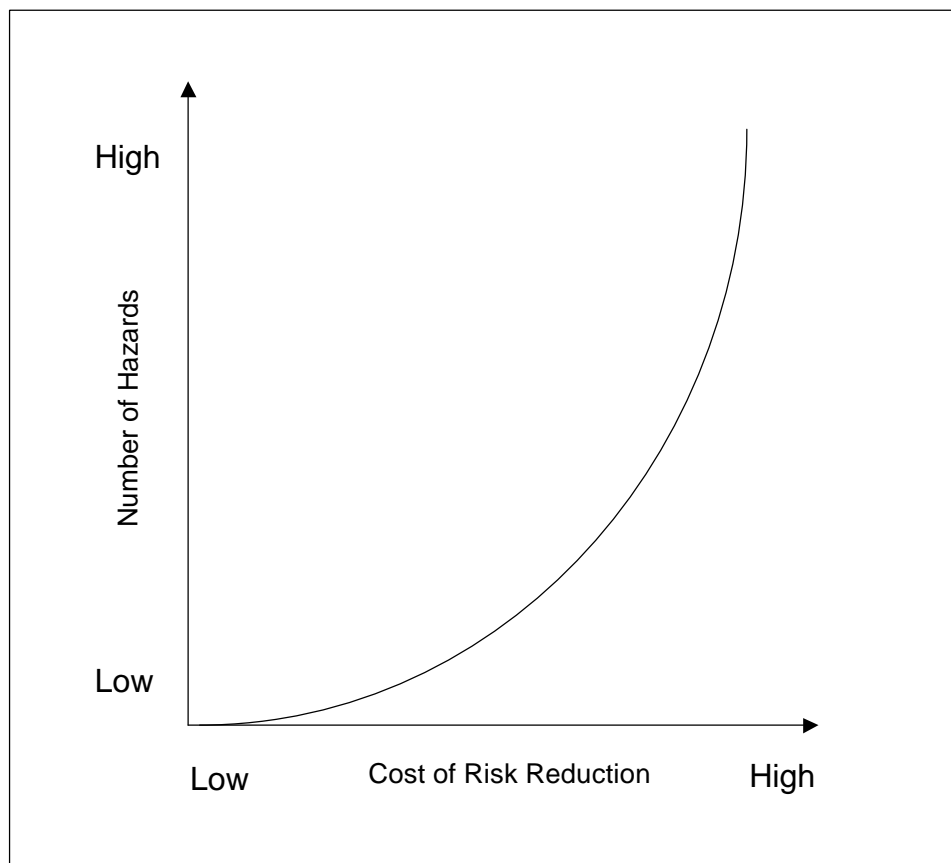
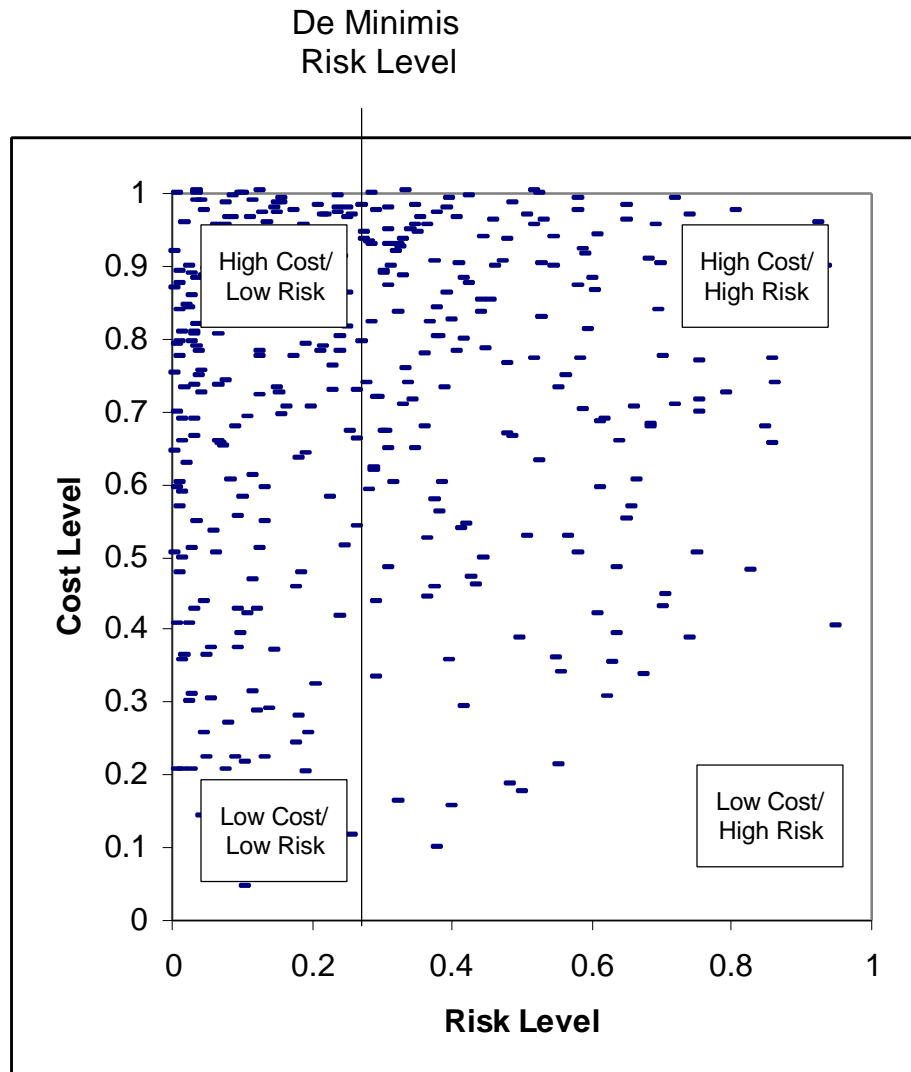


Figure 3. Hypothetical Distribution of Cost of Risk Reduction over different Hazards

Claim:

The de minimis approach does no harm in case of zero correlation between risk level and risk reduction potential and if Figure 3 holds. **Why?**



- It eliminates "high-cost/"low-risk combination".
- It retains "the low-cost/high-risk" combination".

Conclusions With Respect To Old Risks

- Unless if it is far more cost-effective to eliminate very small risks than to eliminate (or reduce) larger ones (Fig 2b), the de minimis risk strategy is likely to help eliminate poorer candidates for regulation and identify better ones.
- It will ordinarily cost less to ascertain whether or not a risk exceeds the de minimis threshold than to conduct more comprehensive analyses customarily required for regulatory decisions.
- The de minimis strategy is likely to save time. Without the de minimis cutoff, regulators may find it difficult to justify decisions to dismiss small risks that come to an official's attention, even if there is reason to believe that better candidates for regulatory consideration await identification.

5. APPLYING THE DE MINIMIS STRATEGY TO NEW RISKS

Previous Arguments apply to new risks as well.

So, why make the distinction?

Answer:

Some plausible scenarios exist in which the de minimis strategy leads to undesirable consequences when used in decisions about whether or not to accept new risks.

5.1. The Incremental Fallacy

- Each additional new risk that is accepted, results in an increase of risk.
- A cumulative series of "individually acceptable" new risks may result in a total increase that is "unacceptable" as a group.

A de Minimis Strategy for new risks should be based on the increase of risk over time due to a portfolio of new risk risks, not on the basis of the acceptability of a single new risk.

Illustration: 10^{-5} Risk level of annual mortality

Condition 1: Single hazard with an annual risk of 10^{-5} is accepted at the beginning of a 70-year period and remains in effect at this level for the entire period.

Condition 2: An additional hazard of the same magnitude is accepted at the beginning of each new year and remains in effect until the end of the period.

Condition 3: An additional hazard of the same magnitude magnitude is accepted at the beginning of each month, or a total of 12 annually, and remains in effect until the end of the period.

Table 1. Lifetime Odds of Mortality

| | Nominal | Condition 1 (Single Risk) | Condition 2 (One New Risk/Year) | Condition 3 (One New Risk/Month) |
|------------------|--------------------|------------------------------|------------------------------------|-------------------------------------|
| Case 1: Annual | 1.00E-05 Threshold | 1429 to 1 | 40.7 to 1 | 3.9 to 1 |
| Case 2: Annual | 1.00E-06 Threshold | 14288 to 1 | 403 to 1 | 34.3 to 1 |
| Case 3: Lifetime | 1.00E-06 Threshold | 1000000 to 1 | 28169 to 1 | 2378 to 1 |

- Nuclear area: proposals for de minimis level involve threshold of 10^{-6} annual risk.
- Outside Nuclear area: proposals have used 10^{-6} lifetime risk lifetime of mortality. Relatively low, equivalent to risk of appendicitis. Ignorable?

5.2. Replacement and Synergistic Effects

- New technologies, products, or processes may constitute new risks that have no effects on existing ones.
- More frequently, new developments introduce new risks while eliminating or reducing old ones.

Examples:

- Replacement of an old drug with a new safer one.
- A new hazard can although thought to be safer indirectly result in an risk increase by interaction with other hazards

De Minimis Utopia:

Thresholds would be defined in terms
of the overall change in the risk.

Note:

- Realistically, a comprehensive approach that considers direct and indirect risk infeasible given normal constraints on resources and information.
- If de minimis strategy for based on direct risk increase:
 1. Harmless if indirect reductions in risk result
 2. Lead to higher level than de minimis threshold if indirect risk increases results.

5.3. De minimis levels and Managing the Flow of New Technology

- Some new products wait in queue for risk evaluation prior to introduction, such as new drugs.
- Most new technologies, products, and processes do not wait in queue for risk evaluation prior to being introduced.

Reason: Rate of new developments simply too fast

Conclusion:

De minimis strategy (= quick and efficient) should especially be considered to screen out low-level risks quickly and efficiently, so more careful attention can be directed to the high-level risks.

5.4. Cost - Benefit Analysis for New Hazards

$$\left\{ \begin{array}{l} \text{Benefits} \geq \text{Costs} \Rightarrow \text{Accept New Risk} \\ \text{Benefits} < \text{Costs} \Rightarrow \text{Reject New Risk} \end{array} \right.$$

- If benefits outweigh costs for a new risk, society may accept new hazards, despite risk increase.

Observations:

- It appears benefits of accepting a new risk generally need to be greater than the benefits of an old risk with an equivalent level risk.
- Giving new hazards a higher weight would allow policy makers to quickly disregard new risks without time consuming value judgments about acceptability.
- Cost of risk reduction for old risks is generally greater than for new risks. It is generally costlier to remove something "entrenched" than to prevent a new risk from starting.

"An ounce of prevention is worth a pound of cure."

- Giving great weight to risk from new hazards than to risk from old ones appears consistent with recent psychological theory and research.

Conclusion:

Different de minimis standards for new risks and old risks may implicitly reflect above observations and sentiments.

6. CONCLUSIONS

- Idea of a de minimis level motivated by the belief that the risk management process currently wastes time on small risks to the detriment of adequate attention to more serious risks.
 - De minimis risk strategy is usually reasonable, especially if restricted to old hazards. Under most circumstances a de minimis strategy will help establish risk management priorities more effectively.
 - De minimis strategy questionable when applied to new hazards. Cumulative effect of multiple new hazards falling under the de minimis level may result in a level of risk substantially greater than the nominal de minimis level.
 - An ideal comprehensive risk management policy would span all types of risks and treat both existing and new ones.
1. Decisions about whether or not to accept new hazards would be based on the same cost-benefit calculus as that applied to old existing risks.
 2. To ensure that the total level of risk for society would not increase a constraint could be introduced requiring that any time a new risk is accepted, an old one of equal or greater magnitude would have to be eliminated.

- Current practice does not constitute a comprehensive risk management system in which new risks "compete" against old ones in the regulatory process.
1. Applications for approval of new drugs do not normally make their case on the basis of the risks of existing drugs.
 2. Risks from insecticides are treated as if they were irrelevant to decisions about drugs.
- Risks arise from such a broad array of sources that a comprehensive, centralized risk management system- may be fundamentally infeasible.
 - If different standards of acceptability for different types risks make sense, then a compartmentalized/decentralized risk management system may be more appropriate than a comprehensive/centralized one.
1. Different de minimis levels for different agencies might be implied, depending on the type of hazard with which they were concerned with.
 2. For the agencies dealing primarily with so-called old risks- "standard-setting"-a different (probably higher) de minimis level may be appropriate than for those dealing primarily with so-called new risks-"screening."
- In conclusion, the de minimis concept is an important concept for risk management. It deserves more attention than it has yet received.