

A Small Dose of Ethics Or An Introduction to Ethical, Legal, and Social Issues in Toxicology



Chapter 4 in Third Edition of
A Small Dose of Toxicology - The Health Effects of Common Chemicals

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Introduction

Rapid advances in science and technology have produced enormous benefits but have also created undesirable hazardous side effects that impact human health and the environment. The toxicological sciences strive to understand and evaluate the health and environmental effects of chemical and physical agents. The impact of this expanding body of science on society has grown enormously in the last 100 years, and with that have arisen corresponding financial, legal, and individual implications. Despite the increased scientific data and understanding, decision-making has become more difficult and complex. It is thus increasingly important to consider the ethical, legal, and social issues that confront toxicologists, public health professional, decision makers, and indeed everyone.

The fundamental principles that an ethical toxicologist should consider can be summarized as: 1) dignity, which includes the respect for the autonomy of human and animal subjects; 2) veracity, an adherence to transparency and presentation of all the facts so all parties can discover the truth; 3) justice, which includes an equitable distributions of the costs, hazards, and gains; 4) integrity, an honest and forthright approach; 5) responsibility, an acknowledgement of accountability to all parties involved; and 6) sustainability, consideration that actions can be maintained over a long period of time (Gilbert and Eaton, 2009).

Beyond these basic principles, it is important to have a vision of environmental health grounded in ethical considerations.

One vision or ethical perspective is that we have “an environment in which all living things have the best opportunity to reach and maintain their full genetic potential”

S.G. Gilbert (2005)

An Historical Perspective

An ethical and philosophical perspective on our work has a rich and evolving history. Looking back, it is easy to the beginnings of an ethical framework for decision making in the Greek physician Hippocrates (460-377 BC), who studied the effects of food, occupation, and climate on causation of disease and is credited with the basic medical tenet of “do no harm”. Bernardino Ramazzini (1633 - 1714), an Italian physician, examined the health hazards of chemicals, dust, metals, and other agents encountered by workers in 52 occupations, which he documented in his book *De Morbis Artificum Diatriba* (Diseases of Workers).

Aldo Leopold, considered by many to be America's first bioethicist, summarized ethical responsibilities in a simple statement in 1949.

"A thing is right when it tends to preserve the integrity, stability, and beauty of the biotic community. It is wrong when it tends otherwise."
(Leopold, 1949).

It can be extrapolated from this ethical statement that exposing people, particularly children, to harmful agents robs them of their "integrity, stability, and beauty", indeed their potential, and is therefore wrong. Health, ecological, and ethical concerns about chemical exposures were highlighted by Rachel Carson in *Silent Spring* (Carson, 1962), first published in 1962. Carson sounded one of the first alarms about the effects of environmental contaminants and catalyzed numerous regulatory changes related to chemical use.

"It is the public that is being asked to assume the risks...the public must decide whether it wishes to continue on the present road and it can only do so when in full possession of the facts..."

"Only within the moment of time represented by the present century has one species -- man -- acquired significant power to alter the nature of his world. "

Rachel Carson

The next major book to capture public attention on this subject was *Our Stolen Future* by Theo Colborn, Dianne Dumanoski, and John Peter Meyers, first published in 1996. This book focused on the reproductive and developmental effects of synthetic chemicals and really raised awareness and concern about endocrine disruptors.

At the same time there were ongoing efforts to define a more philosophical and ethical approach to managing the chemicals we have grown dependent upon. The idea for an Earth Charter was first proposed in 1987 as an approach to creating a broad ethical statement with goal of establishing a global civil society. The Earth Charter took a step forward in 1992 at The Earth Summit in Rio de Janeiro, also known as the Rio Summit, or Rio Conference, which produced the 27 Principles of the Rio Declaration. Principle 15 defined the precautionary principle as an approach to protect human health and the environment. In January 1998 Wingspread Conference on the Precautionary Principle was held in Racine, Wisconsin to define the precautionary principle.

"When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."
- Wingspread Statement on the Precautionary Principle, Jan. 1998

The Earth Charter was being developed during this period and was ultimately adopted by many countries, states, and organizations. Relevant to toxicologists is one of the principles which states: "Prevent harm as the best method of environmental protection and, when knowledge is limited, apply a precautionary approach." The Precautionary Principle as a base for decisions is more readily accepted in Europe, but there are ongoing efforts in the United States to adopt a more precautionary approach in the management of chemicals.

Legal Issues

There is a wide range of laws and regulations that shape the role of toxicology in society. One of the first laws dealing with toxicology, passed in 82 BCE by the Roman Emperor Sulla, was intended to deter intentional poisonings because women were poisoning men to acquire their wealth. In 1880 food poisonings spurred Peter Collier, chief chemist, U.S. Department of Agriculture, to recommend passage of a national food and drug law. The Federal Food, Drug, and Cosmetic Act was adopted in 1938, following an incident in which the Elixir Sulfanilamide, containing the poisonous solvent diethylene glycol, killed 107 persons, many of whom were children. The need to control chemical contamination was recognized in the 1976 when the U.S. Congress passed the Toxic Substances Control Act (TSCA) to "prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances". TSCA became largely ineffective following court decisions and there is now an effort to pass chemical policy reform legislation. In 2016 Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act which was the first major overhaul in many years. In essence this bill did not go into effect because of changes in the administration and the EPA. Meanwhile, Europe has moved forward with REACH – Registration Evaluation and Authorization of Chemicals, a system that requires testing and evaluation of chemicals before their introduction into commerce.

Social Considerations

Toxicologists and public health professionals play an important role in society in protecting and promoting public health. There has been an extra focus on ethical and social issues related to children's health. The U.S. Society of Toxicology code of ethics indicates that toxicologists should be thoughtful public health advocates. While seldom explicitly stated, professional codes of ethics such as that for SOT are often based on the

following social responsibilities: 1) a responsibility to share and use knowledge, 2) a duty to promote the health and well-being of children, and 3) that all species have a right to reach and maintain their full potential.

Other ethical considerations

A toxicologist is also concerned with issues of integrity and honesty in the conduct and interpretation of toxicological studies. It is important to examine and acknowledge conflicts of interests. Toxicology associations as well state, federal, nonprofit organizations, and universities have statements and guidelines on conflict of interest and disclosure. In addition, toxicologists must adhere to rules and regulations regarding the use of animals and humans in scientific studies. The conduct of studies involving humans has a rich history that has become increasingly well-defined and regulated to ensure adequate knowledge and consent of subjects involved.

Summary

The pursuit of ethical behavior and decision-making requires the thoughtful development and articulation of fundamental principles upon which to base any action. The ethical toxicologist must consider and integrate basic ethical principles into their decision-making process. This approach moves beyond what is legally required. An ethical approach requires ongoing discussion and considerations as the toxicological sciences and society evolve. Toxicologists must not only be familiar with the rules and regulations regarding the ethical conduct of research but also the underlying ethical principles. The challenge is to move beyond a purely legal adherence to the rules but toward an ethical approach grounded in carefully considered and articulated ethical principles that drive the responsible conduct and application of research and decision making in modern societies.

More Information and References

Slide Presentation

- A Small Dose of Ethics slide presentation material
www.asmalldoseoftoxicology.org.

European, Asian, and International Agencies

- Ethics of Environmental Health (Routledge Studies in Environment and Health) 1st Edition. Friedo Zölzer (Editor), Gaston Meskens (Editor). Routledge; (2017)
- Environmental Health Risks: Ethical Aspects (Routledge Studies in Environment and Health) Friedo Zölzer (Editor), Gaston Meskens (Editor) Routledge. (2018)

North American Agencies

- US Environmental Protection Agencies (EPA) – Programs of the Office of the Science Advisor (OSA) - Program in Human Research Ethics and Oversight (PHREO) Overview. Online: < <https://www.epa.gov/osa/basic-information-about-human-subjects-research-0>> (accessed: 05 November 2019).
PHREO supports “the ethical conduct and regulatory compliance of human subjects research (HSR) conducted, supported, or regulated by EPA.”
- US Department of Health & Human Services - Office for Human Research Protections (OHRP). Online: <http://www.hhs.gov/ohrp/>. (accessed: 05 November 2019).
OHRP “provides leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research”.
- US National Institute of Health – National Library of Medicine - Bioethics Information Resources. Online: <https://www.nlm.nih.gov/bsd/bioethics.html> (accessed: 05 November 2019).
Provides a broad range of resources related to ethics.
- US National Institute of Environmental Health Sciences (NIEHS) - Bioethics Resources. Online:
<https://www.niehs.nih.gov/research/resources/bioethics/resources/index.cfm> (accessed: 05 November 2019).
Provides a broad range of resources related to ethics.

Non-Government Organizations

- Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). Available: <http://www.aaalac.org/> (accessed: 05 November 2019).
AAALAC is a “private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.”
- American Board of Industrial Hygiene (ABIH). Online:
<http://www.abih.org/document-library#Ethics> (accessed: 05 November 2019).
Applies to all ABIH-certified professionals, applicants, and examinees. ACGIH®, the American Industrial Hygiene Association (AIHA), and AIHA's Academy of Industrial Hygiene (AIH).

- Society of Toxicology. Code of Ethics. Online:
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 Example of professional code of ethics.

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Earth Charter. Earth Summit in Rio de Janeiro. Available:
<http://www.un.org/geninfo/bp/enviro.html> or <http://earthcharterinaction.org/>, Rio de Janeiro 1997.

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http://www.nwpublichealth.org/docs/nph/s2005/viewpoint_s2005.pdf

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Gilbert, S.G. and Eaton, D.L. Ethical, Legal, Social, and Professional Issues in Toxicology. In: *General and Applied Toxicology*. Third edition ed: by Bryan Ballantyne, Dr Timothy C. Marrs, Tore Syversen. Wiley, 2009

Hayes, A. N., & Gilbert, S. G. (2009). Historical milestones and discoveries that shaped the toxicology sciences. In A. Luch (Ed.), *Molecular, Clinical and Environmental Toxicology*. Volume 1: Molecular Toxicology. Switzerland: Birkhäuser Verlag.

Leopold, A.: *A Sand County Almanac*, 1949.

Maurissen, J. P., S. G. Gilbert, M. Sander, T. L. Beauchamp, S. Johnson, B. A. Schwetz, M. Goozner & C. S. Barrow: Workshop proceedings: managing conflict of interest in science. *Toxicol Sci* 2005, 87, 11-4.