# Risk Assessment

Sally Brown
University of Washington

**Risk in our day to day routines**

One could argue that every thing that we do, every day is fraught with risks and that the safest approach is just to hide under the covers. However, staying in bed also has its associated risks. Extended periods in a prone position can lead to muscle atrophy. No access to food and water will lead to dehydration and starvation. Not leaving the bed will involve no changes to sheets and no opportunity for cleaning oneself, increasing the risks of a bacterial infection. And then there is always the potential for the ceiling to fall. So you see, nothing is completely safe.

Yet by and large (some Saturday mornings not withstanding) we do get out of bed and leave the house, potentially by foot, but also by plane, train and automobile. Each of those activities has their associated risks and benefits. Risk assessment is the science of attempting to quantify how great the risks associated with different activities are. When we understand the magnitude and implications of the risks we can make a decision as to whether or not the benefits associated with the activity are great enough to compensate for the risks.

For the vast majority of things that we do on a day to day basis, we are our own risk assessment experts. One example of this is the decision of whether to have dessert after dinner. There is ice cream in the freezer. The decision of whether or not to eat the ice cream is based on a number of factors. These include the cravings that the ice cream will satisfy, the knowledge of the high caloric content of the ice cream and the implications of too many calories for your weight and health. Deciding whether or not to eat the ice cream is risk/benefit based. We can also choose to engage in certain activities that involve risk but find ways to reduce that risk. Deciding to eat the ice cream only if you have gone to the gym that day is one example of this.

**Trusting others**

While in many cases, we are our own experts on risk, for others we rely on the judgment and expertise of others. For example, when we decide to take a particular medication for a headache, we trust that the company that manufactures the medication as well as the Food and Drug Administration have gone through appropriate testing protocols to determine that any risks associated with taking the drug are minimal particularly in comparison to the benefits. When we decide to take a plane, we trust that the airline, the air traffic controllers and the Federal Aviation Administration have done an adequate job to make sure that the plane has been properly maintained and that traffic in the air is appropriately regulated to minimize any risks associated with flying. In each case, the companies and governmental agencies responsible have gone through their own risk assessment and product testing to assure that this is the case. For private citizens we rely on both the integrity of the company as well as the government regulatory agency that oversees the company for our safety.

**Municipal Biosolids**

The situation is similar for municipal biosolids. Although all of us contribute to the production of biosolids, the use of biosolids is generally not something we think about on a day to day basis. For biosolids, there is the combination of federal agencies (here EPA), state agencies (such as the Washington Department of Ecology) and municipal or local government (the POTW or publicly owned treatment works) whose regulations and rule enforcement work to make sure that the risks associated with land application of biosolids are minimal so that the benefits associated with this practice can be appreciated. The National regulations on biosolids are outlined in the EPA part 503 rule. The rule was developed using risk assessment as it was understood at the time. A description of risk assessment, the methods used for the Part 503 rule, and our current understanding of risk assessment will follow.

**The Science of Risk Assessment**

Risk assessment works by trying to evaluate as much applicable data as possible in a quantitative way. The data is used to set up predictive models to determine the probability of a particular outcome occurring as a result of whatever activity is being considered. One example of a simplified version of this is being able to calculate your chances of winning the lottery. The organization that runs the lottery knows the average number of tickets it sells and also knows how many prizes it gives out. These two numbers are used to determine the chances of winning a prize if you purchase a ticket. For real risk assessment, there are a range of unknowns that can influence the outcome of an event. Incorporating information into a risk assessment model reduces the unknowns involved and allows for a prediction of the potential for a range of outcomes. The more information that is included in the model, the better is its' predictive ability. It should be noted here that risk assessment isn't a static science. Methods used for risk assessment change as our knowledge base grows (Schoof and Houkal, 2005).

When scientists carry out risk assessment they also make a range of decisions and assumptions. One of the things that is essential to the process is to decide how conservative or how protective to be. In cases where you are unsure of many variables, it is common to be overly cautious. As more information is gathered, both about the activity that you are conducting risk assessment about and the receptor who is the target of the risk assessment, you have more knowledge and so can be less conservative (also more realistic) in your assumptions. It is possible to make up a risk assessment process to show how this works. You start with a question: Will my skin turn green? With very limited information, the risk assessment process has to use a lot of assumptions. As green skin is a terrible thing, the risk assessment scientists will tend to be very conservative in their assumptions so that you are very careful not to do anything that might result in your skin turning green. As the science of getting green skin gets more developed, more information is available to be included in the model. Things like whether your parents had green skin can be included. Daily spinach consumption and time spent in dank humid environments may also be recognized as factors. The probability model is recalibrated to include new information and to include less conservative and more realistic values for each data point in the model. At the point where all factors involved in getting green skin are understood and sufficient information on these factors is available for the individual in question, the risk of getting green skin turns into a yes or no question. It might turn out that you'll just never dare to each spinach again and will spend as much time as possible on tropical beaches.

**Biosolids and risk assessment**

When land application of biosolids was being considered, a risk assessment was undertaken to determine how the benefits associated with land application compared to the risks. For biosolids, the factors that need to be considered included what was in the biosolids that could cause harm, who or what they could harm and how they could cause harm. Here, how meant figuring out in what ways the dangerous things in the biosolids could hurt people, animals or plants. If the biosolids are land applied and no one or thing every comes into contact with them, there is no 'how' by which the dangerous things in the biosolids can reach someone to hurt them. However, if a person were to walk on a land application site, sit down and eat 5 mouthfulls of the biosolids, there would be a way for the harmful things in the biosolids to cause harm: direct ingestion. As the 503 regulations were being developed, the scientists tasked with evaluating the safety of land application first identified the potentially harmful components of biosolids. They then considered who could potentially be harmed. The whos at that point included people, animals and plants. Then they identified the different ways that these could cause harm. The different pathways are listed below.

When this process was first carried out, toxic organics and metals were initially included as compounds in the biosolids that could cause harm. A total of ten metals and 12 organic chemicals (including classes of chemicals that were structurally similar) were considered in the initial risk assessment. Each contaminant and each pathway were considered separately. The contaminant concentration for the pathway that was the most restrictive(had the lowest concentration of the contaminant) became the limit setting pathway. It ended up that organics were left out of the regulations for the following reasons: many had been banned and concentrations in biosolids were well below what would have been regulatory concentrations.

In the original risk assessment process for biosolids, the scientists used all available data to make the risk assessment as quantitative as possible. However, there were still many unknowns in the process. As a result, the scientists conducting the risk assessment were very conservative. For example, in defining the person at risk for harm from biosolids, they picked someone who ate 60% of all of their food including their meat from soil that consisted only of biosolids for a 50 year period. The acceptable risk for this person was considered to be no greater than a 1 in 10,000 chance of illness from the biosolids. It ended up that direct ingestion of biosolids by children was the most limiting pathway for the majority of the inorganic contaminants.

Since the 503 regulations were written, the science of risk assessment has evolved. The EPA recently revisited the need to regulate dioxins. In the dioxin risk assessment, EPA used the more developed risk assessment process than had been used for the 503 regulations. Instead of considering all pathways separately, the potential for a person to be exposed to dioxins via multiple pathways simultaneously was used for the model. The risk assessment focused on farm families for this process with exposure possible through air, soil ingestion, both above ground and below ground produce, beef and milk, and poultry and eggs. Transfer of dioxins through breast milk and eating fish containing dioxins were also included. The US was divided into different moisture and temperature areas and different transport and food chain models were developed for each region. EPA determined that the greatest risk was related to beef and milk consumption. The acceptable risk that was used was 1 in 100 000. The number of people that would potentially fall into the scenario that EPA tested for was about 1600. The decision was made that it was not necessary to regulate dioxin concentrations in biosolids.

Although the risk process used in the development of the 503 regulations is no longer current, the process that was used is overly conservative by today's standards. This means that using modern risk assessment techniques would not result in decreasing the concentrations of the identified contaminants in biosolids. As we understand that there are additional constituents in biosolids that can potentially cause harm to people or the environment, additional studies are undertaken to understand the behavior of these substances in biosolids amended soils. One of the things with science based regulations and science based risk assessment is that it isn't a static process. As our understanding increases, we have the potential to revisit the regulations and refine them. The process to decide whether it was necessary to regulate dioxins is one example of this. In addition, since the 503 regulations have been enacted, two National Academy of Science panels have revisited the regulations to see if they are still valid as our scientific understanding has improved. The regulations are holding up fine.

Schoof, R. and D. Houkal. 2005. The evolving science of chemical risk assessment for land-applied biosolids. J. Environ. Qual. 34:114-121

USEPA, 1995. A guide to the biosolids risk assessments for the EPA Part 503 Rule. EPA 832-B-93-005. Office of Wastewater Management, USEP, Washington., DC.