Life Cycle Assessment Prof. Brajesh Kumar Dubey Department of Civil Engineering Indian Institute of Technology, Kharagpur

Lecture - 06 Risk Assessment and LCA Frameworks

So welcome back to the second week of this particular course, which is on life cycle assessment, in this week we will be as I said towards the end of last week the last set of last video that we saw we will look at some of these risk assessment the concept and how it relates to the life cycle, and as you know for every week we have 5 videos of 30 minutes each. So, this week again we will start with the first module of the second week and where we will cover the basics of the risk assessment.

So, next around 30 minutes I will try to give you a brief overview of what is the risk assessment, and how it is done and we will have a there is I think there is another video will come up later on when we will look at in some details, but here we will cover the basics.

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Introduction

- Sustainability issues are complex, and understanding their interactions with equally complex engineered systems is best done through well-structured analysis frameworks
- Risk-based frameworks have traditionally been used in the characterization and prioritization of environmental issues
- Increasingly, however, life-cycle frameworks are gaining prominence as a means of characterizing and understanding sustainability

So, as you already there I do not have to kind of say that again you already would have got an idea in the week one that sustainability issues are complex, and understanding of the interaction of the complexity as you saw towards the last during the last week water, food, energy they were all they are all complex and that so that it is an equally complex engineer system. So, and understanding their interaction is very important and that is why you do by coming up at some analysis framework. We have been talking about environmental health human health, but when you do this environmental health and human health one of the important concept is the risk assessment concept. So, when I say something is bad how bad is, what is the risk from that whether it is affordable risk whether it is a manageable risk, if it is whether it is an unmanageable risk. So, it is a we have to come up with the risk based framework to characterize as well as to prioritization the environmental issues; and this we again when we try to do that we use life cycle frameworks we use the life cycle frame works in terms of characterizing and understanding sustainability which you will see in this particular week during the discussion in this week.

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So, what is risk? So, risk is defined as the potential of for an individual to suffer an adverse effect of an event, and the concept of risk is used in all analysis those of you are familiar with the financial you hear that financial risk assessment or financial risk, and you talk about the share market many times you hear that share market this this shares are it is a risky share like a high risk high again, or low risk low again kind of a where this is really a good company you invest here that return will be there. But may not be very high some companies are there which will give you a lot of return, but then at the same time you have a chance that you may end up losing your money so that is a concept used in the finance.

In engineering risk we talk about an engineering a risk as well when we design like a road safety issues, any issues any is issues that you have to you have some risk associated with that essentially the potential for an individual to suffer an adverse effect from an event there is a health risk; so in the precise definition of risk and where it depending on the application. So in terms of understanding the language of risk and the tools to quantify the risk, and the use of risk in the regulation; so we have to understand the risk framework, and how it can be potentially employed for environmental and sustainability issues.

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Environmental risk Environmental risks, can be grouped into three general categories: • Risks involving voluntary exposure: Activities done for a living or for enjoyment (firefighting, skydiving, mountain climbing, bungee cord jumping, etc.). The risk (danger) is usually obvious and the activity is usually done by free will. Risks associated with natural disasters: Floods, hurricanes, earthquakes, meteorite hits, and other disasters beyond human control. Exposure to the effects of certain natural disasters can be exacerbated by actions such as living on a known earthquake fault or the slope of a volcano. • Risks involving involuntary exposure: An individual or entity releases a compound into the environment (pesticides, known carcinogens), potentially harming workers or members of the public, who cannot directly control the exposure

So, that is what we will try to look at as part of this particular module; here again lot of slides since you will be getting a pdf version of these slides I have left those text in there, but do not you do not have to try to worry too much about kind of reading those test right now, while you are listening to this video. It is environmental risk can be grouped into three general categories and you just look at those bold points that has been made here, one is the risk involving voluntary exposure. So, that is where you do it voluntarily say you want to go for a bungee jumping, and the bungee jumping is skydiving mountain climbing those things these are the risk you know the risk is there, and your risk is obvious, but you want to take it is your free will to do that.

But then there are risk associated with natural disaster; that could be flood that would be earthquake, hurricanes and some kind of meteorites hits other disaster be these are beyond our control in a direct sense, and these are and there could be some exposure to certain natural disaster, and this is what is going may happen. So, that is the risk associated with natural disaster as very self-explanatory, then risk involving involuntary expression that is what we are kind of talk about. When you are talking about chemicals released in the environment, when you are talking about different air pollutants those are not those are involuntary, say you and me does not want to inhale toxic fumes in the gas in the air.

But or like in received in finance in industrialized towns, the towns with big lot of vehicles especially the metropolitan towns in the country, if you go to Delhi gets lot of new lot of a news on air pollution issues; say if you are living in Delhi you do not really want to inhale those toxic fumes or toxic chemicals which is present in the air there, but the problem is you do not have any other option, you have to inhale and exhale to survive. And to inhale you will get all these potential harming chemicals in there. So, that is your involuntary exposure, same thing the world think about the workers working in the industry those who are they are working in the industrial setting which has lot of chemical things being released into the environment because of some leakages and other stuff, and then they are exposed to it. So, and we cannot have directly control on the exposure, because we can put some mask and other stuff but even after that there will be some exposure.

So, that is what those are our involuntarily risk involuntarily exposure from risk coming from there. So, that and how this involuntary exposure comes because of the release of chemicals to the environment.

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And the chemical gets released to the environment because of the release to the atmosphere, release to surface water release to land. And when we talk about the environmental risk it is the function of hazard and exposure. So, if you like a mathematical equation for environmental risk, it will be a function hazard and exposure are your two variables. So, if some chemicals are there it is a very high high hazard potential.

But the exposure level is very very very very low, you may have less environmental risk. But at the same time some chemicals are there which is has a hazard potential like a medium level hazard potential, but the exposure is very high. So, you are exposed to it say 5 6 7 8 hours a day, then your risk is pretty higher from that even although the hazard is not that high, because it is the function of the two it is a hazard as well as the exposure that is all your the environmental risk is calculate.



So, risk is the likelihood again as we said earlier likelihood of harm, it could be both short term as well as the long term if you have read any of these books you know the short term we call acute and the long term we call chronic. So, it could be both cute as well as chronic there could be and there is a chronic effects and the effects on human health, and the quality of human life also the ecological systems, economic systems because if you have if you have a unhealthy work force. So, work force you will have an unhealthy economy, your work hours will go down and people you will have a impact on your economic system as well.

So, the risk assessment what we do we use a process by which the form dimension and the characteristics of the risk are estimated, and I think the week sorry this particular week on the third module you will hear you will see some of the details of how that is done. And we utilize both qualitative as well as the quantitative approach; if you do not understand the difference between qualitative and quantitative quantitative is with the numbers, qualitative is where you have a feeling of whether it is a good or a bad, but you do not you cannot say the numbers associated with that. So, we are many times you want if you cannot have quantitative information qualitative information is good but we would like to have quantitative information more than qualitative ones. And then if you once you assess the risk you have to manage that risk; sometimes you cannot really what you can say you cannot really take out the risks. So, you cannot really like a remove the risk from there so, but whatever is the risk you are trying to manage it, you are trying to control it, you are trying to reduce it as much as possible.

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And it is a many it is a regulatory decision risk are based on regulatory decisions, there are if it is a cancer say some of the risk for example, for marcie or from cyanide from other stuff if it is a cancerous, carcinogen, benzene for example, if it is a cancer in point usually we use a risk of one in a million.

So, we want to go down to the level. So, for example, arsenic drinking water standard is 10 micrograms per liter right. Earlier, it was 50 micrograms per liter, but with better science we have reduced a drinking water limit to 10 micrograms per liter right now. So, the 10 micro grams per liter is based on the principle of one in a million cancer risk, now what does that mean? That means, that if our drinking water has less than less than equal to 10 micro liter micro liter per micro max 10 liter micrograms per liter, and if somebody is consuming that water throughout it is life there is a chance of one out of a million population that person will have a cancer because of this.

Since the cancer can happen with many other factors as well, but it just from the arsenic exposure there is a chance of one in a million, that is based on some of the work that is done with other species like a rat, genepics and all those mice and then you extrapolate you do a some a statistical analysis and you do an extrapolate those values. There are

epidemiological basis for a human risk calculation as well, if you have the epidemiological data; epidemiological data means data from exposed population.

In case of arsenic we have the exposed population in Bangladesh, we have the exposed population in part of West Bengal we have this exposed population in Vietnam Taiwan and several other countries. So, we can get the data from there that is from the real like the real field data and we can correlate we can see how our lab data fits with the field data, and then we can learn from that and we can come up with a better to risk assessment of that. Animal testing is done as I said earlier where human data is unavailable, most data are animal testing data except in those rare situations where human exposure event has been documented; and where you have this human exposure even documented that is called your epidemiological data.

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| Familiar Risks | |
|---|--------------------------------------|
| Reference point = 1 in a million (1x10⁻⁶) below which USDA doesn't consider risk from a food a | dditive to be a concer |
| Minimal risk = 1x10 ⁻¹⁰ to 1x10 ⁻¹² Very high risk = 1x10 ⁰ to 1x10 ⁻² | |
| Examples | Risk |
| Drowning in a tub/year | 10 ⁻⁵ to 10 ⁻⁶ |
| Death in airplane crash | 10 ⁻⁵ to 10 ⁻⁶ |
| Death by automobile accident | 1.7×10^{-4} |
| Death by lightning strike | 10 ⁻³ to 10 ⁻⁴ |
| Death from smoking 1 pack/day | 3.6×10^{-3} |
| Cancer from 1 lite beer/day for 1 year Cancer from 1 peanut butter sandwich/ | 5 x 10 ⁻⁵ |
| day for 1 year | 1 x 10 ⁻⁵ |
| Cancer from charbroiled steak/week for | |
| 1 year | 7 x 10 ⁻⁶ |
| Cancer from drinking water with 80 µg/L CHCl3/day | 6 x 10 ⁻⁷ |

There are risk is there and everywhere there is a reference point as I said it is one in a million, below which USDA does not considered risk from a food additive to be a concern. If it is a minimal risk is considered 10 to the power minus 10 to 10 to the power of minus 12, that is a minimal risk very high risk is 1 to 0.01 So, 0.01 to 1 is considered high risk; and there are risk associated with different aspect like if you take shower in a tub drowning in tub per year it is around 10 to the power 5 minus 5 to 10 to the power minus 6similar to death in an airplane crash.

So, we do hear from time to time the airplane has crashed, but the risk is pretty low based on the aero plane technology as of today. Automobile accident it depends on which place you are, but automobile accident as you hear in Indian context lot of people die in every day we have people dying because of the automobile accident, it is around 1.7 10 to the power minus 4 death by lightning 10 to the power 3 to minus 4 again death of from a smoking one pack of cigarette per day 3.6 times 10 to the power of minus 3. This as you go down you see different different cancer for one liter of beer per day for a year, cancer for one peanut pea nut butter sandwich peanut butter sandwich actually many people in the world especially in the western world, they have peanut butter energy. So, that kind of leads to that cancer from char boiled steak cancer from drinking water with 80 microgram per liter of ChCl 3 per day.

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So, there are as you can see there are different risk out there which people are used. The basic principle of risk assessment is first of all we need to determine the probability that a adverse effect will be produced, and all human activities will have some risk concern mostly with the rest from exposure to chemicals that is why we are following up, then risk assessment in terms of the extended definition, it is a methodological approach where your chemical exposure are identified, you look at the analysis for the dose response relationship and then you try to quantify. How we do that you calculate the amount of chemicals absorbed into the human body, then compare the absorbed dose with the EPA safe dose for carcinogen for non carcinogen it is reference dose, EPA dose

not recognize the safe dose for carcinogen. So, any level of exposure has some kinds of risk from there.

So, risk is specific dose is used to EPA to expose. So, basically based on if you know what is the chemical absorbed into the human body, and then for the non carcinogens if you know what is the safe dose, we can calculate it we find out what is the risk.

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So, carcinogen again we have a risk specific dose is used for EPA to expose to come up with the risk factor; this is a typical curve which you may have seen in your previous some of the courses as well it is called dose response curve, as you can see from the bottom of this curve over here on that on the x axis you start from zero, and the line of kind of gets up after this threshold dose, you see the increasing effect showing up.

So, initially there is no affect up to this point. So, no effect up to this point means you keep that is called the no effect region, and many times you hear the term NOEL, no absorbed effect level and then this will be your first like when you start seeing effect and then your effect goes up up up and up and then you have a maximum effect and after this even if you keep on increasing the dose, your effect does not go up. So, it could be the final, it would be what is the maximum effect it could have. So, in the middle is what is the range of increasing effect with increasing dose. So, as you increase the dose effect goes up. So, here you can calc also calculated what concentration you will have 50

percent of the inhibition, 20 percent inhibition and all those things can be done on that pic on that like with this data.

Usually this data is generated from testing those like lab species which we talked about earlier. So, this is your typical dose response curve it is also known as s curve as because of the shape of the curve and this is used a lot in terms of a risk assessment of both carcinogenic and non-carcinogenic.

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| Cancer Risks | |
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| In the history of epidemiology, only a few environmental agents have been repeatedly, and strongly linked to human cancer - Cigarette smoke Alcohol Ionizing radiation Some drugs Some occupational carcinogens Asbestos, solvents, benzene Viruses Hepatitis-B, human T cell leukemia virus, human papilloma virus | |
| | |

In the history of epidemiology only a few agents have been repeated. So, linked to the human cancer for example, cigarette smoke, there is lot of data on cigarette smoke alcohol, ionizing radiations, some drugs some occupational carcinogens asbestos solvent benzene some virus like hepatitis B, human T cell leukemia virus human papilloma virus.

So, these are some of the viruses some of the stuff on the cancer risk, which has been reported. So, you can you will have some of the epidemiological data associated with that.

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So, many epidemiologists require increased enough increased risk by a factor of three to take new cancer risk seriously. So, anything more than three to take it is seriously; anything less than three you do not take it seriously anymore. So, for example, of risk high cholesterol diet and you see here gender in the middle for male, high cholesterol diet there is a risk ratio of 1.65 for the colon cancer, very fact that it is for the female around this ratio of two for the breast cancer vasectomy, there is a chance for 1.6 for the prostate cancer, if you have a tap water with chlorine 3.3 liters per day, you have 2 to 4 risk ratio for the bladder can bladder like a cancer risk psychological stress for both male and female 5.5 that can lead to a colon and rectal cancer high saturated fat diet.

Again you will have for the female sex, for the nonsmokers, for the lung you have a lung issues red meat 5 times a week for both men and female a chance of a 2.5 is risk ratio got it should be 2.5 should show up over here in the colon is the side. So, this got switched a little bit on that side that is your; so, again, these are some of the risk ratio just to give you some examples of different risk of a different stuff.



So, in terms of the risk definitions there is a applied dose you saw the dose response curve. So, applied dose is the amount of chemical in a medium that is available for update.

So, how much chemical is available absorbed dose is the amount that chemical get absorbed, whatever you chemical you apply this does not get absorbed. So, that is why when you take a medicine say if you get a prescription drug, so when you go and buy this medicine you have a 100 mg template tablet, 600 mg tablet your body may just require say 10 mg or 60 mg, but you are using a 100 mg tablet or 600 mg template because things only part of it will get absorbed in the body rest of it will just go out of the system.

So, related to the fraction of the applied dose that is absorbed you need to consider route of exposure, some will you can have a injection you can take the food through that the medicine skin, that is another way you can get some absorbed that have exposure to certain chemicals inhalation you inhale something. So, the reference dose is the dose of a non carcinogenic that is believed to be safe for human. So, you take the animal toxicity data, and then you extrapolate it to human using some statistics with that.

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Now, we have a risk specific dose; the dose at which one person in a million exposed will develop cancer that is for the carcinogen they were one made in a million cancer risk, when we calculate hazard index which is the ratio of absorbed dose to the RfD.

If the hazard index is less than equal to one it is it is an unacceptable situation, but if the hazard index is greater than one; that means, a chemical concentration needs to be decreased. So, that is where the risk management comes in picture where we have to factor this risk assessment and then look at what are the possible alternative action. How much chemical exposure can be reduced, and what will be the cost associated with that what is the cost benefit considerations associated with, what is the need for the consumer alternative chemicals.

So, then how best to regulate exposure to the chemical should we having a better personal protective equipment, sometimes it may not be possible to reduce some of those chemicals in a factory setting. So, in that case you need you will probably use better personal protective equipment, so that it you as a worker in they are not getting exposed to it.

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So, in terms of the risk assessment process at site with say for the drinking water, first of first thing we need to do is to find out what is the hazard, what is what chemicals are present, what chemicals are present and what is the concentration of the chemical. So, towards the end of this week that was the later part of this week I will tell you how we can analyze for these chemicals, and how we look at this concentration and some of the statistics associated with that. So, the first thing for any of these risk assessment processes says in terms of what is the hazard.

What chemicals are present at what concentration, whether it is a carcinogen non carcinogen then you try to come up with that dose response curve with the animal data mostly with a animal study data, and you come up with the dose response relationship probably you may have to repeat the experiments for the data validation compare the day effects and similar chemicals have been studied elsewhere, compare the count results discover the RsD, RfD or the RsD data from the animal studies which would be used.

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Then once you have the animal data of you need to ex make some assumption because in the absence of epidemiological data, we need to take the animal data and extrapolate it to humans. So, for example, in the drinking water scenario we need to make some exposure assumption. Important exemption exposure assumption ok could be that how much water an adult will take per day on. So, upn an average 2 liters per day adult weight around 70 kg, assume that water has a 0.5 milli grams per liter of zinc in the drinking water.

So, point five milligrams per zinc 0.5 milligrams per liter of zinc in the drinking water, an adult consuming 2 liter per day with it is with his weight or his or her weight being around 70 kg. So, we can calculate the dose where you have whatever is the load coming in 0.5 milli grams per liter multiplied by 2 liter that is the amount of zinc that goes into the system through the drinking water source, divided by 70 kg is the weight. So, in terms of this litre this will go away so you have a round 0.0143 milligram of zinc per kilogram body weight per day.



So, then we need to say whether it is a we need to compare this number with the reference dose number, which is already been most of the most of the non carcinogenic you will have find the data already available at certain websites VPN and other regulatory websites; then you can do the risk estimation. So, compare the dose to RfD clean up required if the risk is greater than one in a million for cancer or hazard index is greater than equal to one for non cancer for zinc for example, RfD is 0.2 it is a non carcinogen. So, you find you try to find out hazard index. So, 0.2 is safe, the dose you are providing is 0.0143 number comes out to be 0.0715. So, the hazard index is less than one. So, no cleanup is required.

So, water assuming that no other significant contaminant is present. So, this is how you will do the risk assessment procedure.



So, in terms of development of this reference dose we just now in the previous example previous problem, we use the reference dose number for the zinc. Where this how this reference dose number came in, a reference dose came numbers comes in from that dose response curve which you saw earlier in the slide in the presentation.

So, in terms of the dose response you have the NOAEL and LOAEL, NOAEL is the last no observed adverse effect level and then your LOAEL is the lowest observed adverse effect level. So, you divide this NOAEL or LOAEL by an uncertainty factor; why uncertainty factor because you are going from animal species to a human species and there are other things as well as is listed at the bottom of the slide, there are uncertainty factors if the data uncertainty a high to low dose extrapolation, and then we have a intra species extrapolation you are going from one species to another, then there are extrapolation between routes of exposure and for protection, then another factor of 10 for protection of sensitive individuals because for the same for example, right now if you have change in weather and some people catches cough and cold very quickly when there is a change of weather.

So, for the same change of weather other person may not catch cough and cold, because different people have different immune system. So, some people are sensitive. So, to take care of them we put a protection of them and over there as well. So, if a dose has no adverse effect on a mouse at 0.5 kg per 0.5 milligram per kilogram today, then divide by

10 to the power of three for safe human dose you get 0.00005 milligram per kg per day. So, that is how you calculate the RfD.

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For like a maximum contaminant like a maximum contaminant level goal for drinking water for carcinogenic problem carcinogenic we have at 0, for non carcinogen may we have a drinking water equivalent level divided by the slow fact. So, this is what we use here and a category three if you have no carcinogenicity no impact we do not have to worry about that.

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So, in terms of how will you calculate this dual and MCLG drinking water limit? So, you establish NOAEL from the literature or from the experiment, you calculate your RfD which is the NOAEL divided by the slope factor, dual assumes no carcinogenicity and exposure medium in water.

So, you have RfD body weight and the little of water; for the mcl this is for carcinogen we have zero, for this we assume a food intake besides water. So, based on that you need for MCLG for whatever the drinking water number, minus the food contribution, minus the air contribution; so that is what you get for a basis for second type of contaminants you multiply the drinking water contribution. So, that is how you calculate it. So, again if you look at this particular is in terms of calculation, we I will kind of rewind like a I will go over this like one more time to make it to give you one more explanation to make it more clear.

We have two categories you can say three categories of pollutants; category one is a known carcinogen or probable carcinogen. For which we do not want any of these to be present in water, for category two which is your some sort of impact is there, but no if they are not carcinogens. So, there we take the drinking water equivalent level and then divide by slow factor. Slow factor is a simply I have your risk factor a factor of safety; then category three where no evidence of any carcinogenicity where you have goal is equal to the drinking water equivalent level.

So, we are at that particular level. So, how you do that you establish NOAEL and LOAEL from the literature, multiply it by the slow factor and then you get that number RfD number, calculate your drinking water equivalent level based on what is the body weight on the liter of water ingested for the different categories you find out, and then water is not the only source you have the food contribution and air contribution as well, similarly like for like the second basis where no such impact we can take in terms of the percentage drinking water contribution from there.

So, with this we kind of cover this particular segment of this module, where we have looked at in terms of a quick summary we looked at the basics very fundamental aspects related to the risk assessment; what is the definition of risk assessment, how we go about and doing for a carcinogenic chemical non carcinogenic chemical, how the data come from and what are the issue how you go from animals animal data like a rat, guinea pigs and those data to the human data and some of the calculations associated with that in terms of the drinking water limit. So, drinking water equivalent level how you can calculate whether something is you know the dosage, how to calculate the dosage at the same time if you know the dosage how to find out whether it is a safe you look at your hygiene index, you also look at other factors associated with that and then how come up with your decision.

So, that is summarizes the basics of risk assessment we will again on the third module of this particular week will kind of go a little bit of more detail on the risk assessment part, but for now.

Thank you and keep watching this video.