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Lecture – 08 Risk Assessment Methods

(Refer Slide Time: 00:26)



Welcome back. So, in the previous module we were talking about the cancer effect. So, here we will start with the non cancer effect. So, if you have a, as we talked about the in the earlier module as well, that when you talk about any impact coming from any chemicals you can have cancer impact, that is the most predominant one which we get we get worried about a lot. But at the same time there could be non cancer effect too because, non cancer effect also leads to the problem, if you may have a liver issues certain things do impact liver nervous system problem, the whole issues of led that, if you go on a petrol pump you see unleaded petrol or unleaded gasoline, that unleaded means what? There was a led some times in our petrol.

But, we have we do not use that led any more. The reason for that led being not used in the petrol or even in led based paints. Many of the buildings are painted with paint that we use, those Asian paint and Dulux paint and all those different brands that we see. Many of those brands used to carry led, now we are facing out of the led. We do not want being expose to led. Led is considered very bad for our impact on the nervous system and a small kids, especially for the small kids for the led it gasoline led it petrol the problem was the, if you look at the exhaust pipe of any of these automobile whether it is a 2 wheeler 4 wheeler you see the exhaust pipe is at the bottom and that is at the level where the small kids will walk and all. So, if you have the exhaust coming out of these automobiles, if your car and it goes into a very low level on the road, that is where our 2 years old 3 years old and 4 year olds that is the level they are. So, they are taking all these led in their smoke coming into their body specially when they are waiting for say school bus and all that.

So, and that impacts their nervous system, later on I will show you some slides like how it impacts. It is been already documented by research and all that and there are certain chemicals like cadmium even iron at a very high concentration I all though we need iron, but iron at very high concentration, at a concentration of more than say 4.2 milligrams per litter in our water or it may have an impact on kidney. So, there are things which impact kidney as well and there are things which impact reproductive system. A boron is one of them, boron is say that boron has a impact on the reproductive system we do not and we use this glass that we use many of those glass has a borosilicate glass, borosilicate is it is a boron and silica.

So, if your glass is not of a good quality, the glass that we use for day in and day out for drinking water or drinking the tea, if it leaches little bit of boron that is with your tea or water, you are getting little bit of boron in your body and that actually has an negative impact on our reproductive organs. So, that is again or these days newer one of the newest property here about is those thailets. Thailets are coming from those plastic pipes. So, plastic bottles again those thinner bottles, thinner plastic bottles it has lot of, it has thailets are there. So, that is be a fair of this finale those are other chemicals which has impact and there are some which has an impact on the developments. So, people development gets block because of so, these are non cancer effect these are these are not going to cause you cancer, but at the same time this has an impactant impact. So, you certain organs are getting impact, reproductive system may be getting impacted and also the development side of it.



So, whether it is a or like a cancer carcinogen or non carcinogen, how to we quantify toxicity and part of it we talk about the yesterday as well is like a being the first module as well in terms of quantifying the toxicity, it is natural to quantify how toxicant chemical is. So, we can control the level of this pollutant. Why we are interested? As I said very, in the very beginning of this class for anything that you learn, you need to always try to think about why it is important? Why we need to, why do we need to quantify toxicity? How we can always figure it out? We need to quantify toxicity so that we can control the level of this pollutants entering the environment. So, if you know how bad that chemical is, we can control we can reduce the chemical either we can reduce the chemical concentration if we can do that or the other ways we can limit the exposure.

Many places for many work place especially where the lot of sound and other stuff they do not have 8 hours work day they have actually less number of. They work for less number of hours because, they do not want people to be expose to all that sound around them for 8 hours per day because it is bad for them. So, coming back here in terms of the controlling the level of this pollutant entering the environment. So, the toxic effect is potency times exposure. Potency means how bad the chemical could be and the exposure is how long you are exposed to it. So, it is not just how toxic chemical is it is also how much of an organism is exposed to that chemical. So, both are important, if the chemical is highly toxic as our telling you in the just previous module. Even if the chemical is highly toxic you walk in to a room and you came out and the, but you had a very low level of exposure.

So, if you look at this particular equation over here, even if the potency is too high, if the exposure is very low, the product will be low product will be less say potency is medium, exposure is medium the product will be high. So, as if the potency is very low, but the exposure is very high again the product will be high. So, it depends on it is a product of potency and exposure that it takes what would be the toxic effect from that particular chemical.

(Refer Slide Time: 06:17)



So, then how do we quantify the toxicity? We look at the data, when data regarding the toxic impact that, we look at the data and the data has to come from somewhere. So, if you remember from your biology class, even if the high school level we have done some dissection of animals, we look at how the different like frog and tore and sometimes even mice and rat and as you go in higher level classes you have genomics rabbits, sometime even in some places in the world they have use monkeys, because monkeys is a very close to humans in terms of their bell.

So, monkeys where used, monkeys where fed arsenic for example, monkeys where fed certain chemicals and look at how where this arsenic is ending up, whether in the liver or in the tissue, how much in the liver, how much in the tissue. So, that you can try to find out what can potentially impact it may have to the human body. So, when the data

regarding the toxic impact are gathered from the laboratory studies or from epidemiologically study. Again epidemiological as I was trying to mention it earlier it is the data which is coming from the exposure to human population. We have some data now in terms of arsenic exposure in Bangladesh, Thailand, Vietnam those places so that is the epidemiological data. So, that is your and the information is gathered and we taking the information. We look at the degree of the toxic impact at different level of exposure since we cannot have different level of exposure kind of data of being exposed to human.





So, we put a lie on animal studies and from the animal studies we extra pollute it to the humans. So, and then once you do the animal study you come up with this graph. So, you have this y x axis which is the exposure and your y axis is the toxic impact. So, when you start your exposure, when you start at the low concentration, you first 3 dots you do not there is no impact, that is why here we do not see any impact, there is no toxic impact after this level the impact is starts building up then when you increase the exposure again, it could be either you can increase the chemical concentration or increase the duration both you will lead to a increase an exposure and then at the certain level it kind of tappers often again it becomes a flag.

So, this is your, what is known as the dose response curve. I showed you this curve earlier in module, this is the dots dose response curve and this is how it is prepared. You

feet your animal species in the lab at different concentration or you increase the duration of exposure. So, duration of like exposure to that particular chemical and then you see the rocky up to a certain level no impact. If I increase the exposure level further I start in the impact when I go to a certain level certain concentration or certain exposure level after that it starts stiffening off. So, this is your typical x curve for a dose response. So, and then the point where you do not up to this point is your no observe impact. So, this is your no absorb impact level. So, this is a, such different terminology used for that this is your NOAEL. NOAEL is the no observed adverse effect level. So, that is the NOAEL, no observed adverse effect then we have a term called LOAEL. LOAEL is at what concentration at what exposure you start in the impact. So, this is your lowest observed adverse effect level.

So, at that concentration we starts saying some impact coming out and then we can look at EC 50. EC 50 is a syncline we are trying to say that exposure at which effect occurs in 50 percent of the population. So, if you are running a experiment with 10 different 10 fish and you see the impact in 5 fish at certain concentration or certain exposure level that is your EC 50. So, that is your effective concentration or effective exposure at which effect occurs in 50 percent of the population. So, that is the EC 50 and when you go up here we are basically seeing 100 percent impact thus you complete impact. So, again x axis is the exposure, y axis is the impact. We start from no impact and then it start seeing increase and then we starts in the flat in this particular curve is typical as the shape, as you can see it is as shape like the slightly stressed as and then this is called dose response curve, which is one of the very important concept in toxicology as well as in the risk assessment.

(Refer Slide Time: 10:59)



Now, this data came from a lab study. Now, if you look at the epidemiological data, say data coming from Bangladesh a part of west Bengal or part from Vietnam, Taiwan regarding arsenic exposure. You do not have the luxury of getting the data at very low concentration up to very high absorbable level, what you get is basically whatever you found from their like, sample somewhat kind of samples we are talking about blood samples, may be urine sample, for arsenic even we look the hair sample, nail samples. So, if those things are those things are collected and then look at what is the potential impact coming from them. Then you come up with these 2 data points, now this 2 data points are giving us say very high level of impact already and at a certain level of exposure.



Now, the thing is that what will happen if we have a lower exposure? We will come back to the graph and try to explain it. So, we can estimate the effect as a result of exposure, but what exposure is acceptable. So, it is for different for cancer and non cancer effect we handle it differently. For non cancer we basically, it is a protective exposure in one is one with no effect. So, wherever we do not want exposure where we see any effect coming showing up. So, it is a non cancer effect with its protective exposure in is one with no effect showing up. In cancer effect here we as I was explaining you in the earlier module we take the acceptable rest of 1 in a million cancer.

So, if you have a 1 percent out of a million people, why we do that? Because say if you want to go even further say 1 in a from 1 in a million, to say 1 in 10 millions, 1 in 100 millions the cost of treatment goes up again if you see the drinking water limits which is we are always like drinking water we need water from day and day throughout the day. So, when you are drinking the water what the water is supposed to be meeting the drinking water standard and if you are not familiar with drinking water standard, you should get familiar with that and our encourage you to can read about it. So, drinking water standards are based on certain like a acceptable exposure level and that is exposure level for a carcinogens is 1 in a million.

So, for example, in arsenic we went from 50 micro grams to 10 micro grams per litter. So, right now arsenic drinking water standard is 10 micrograms per litter, headily we do not want any arsenic as do not like to have 0, but the problem is we cannot there are couple of problems here number 1 we cannot measure 0, we cannot really say that this concentration is 0, because no instrument can gives us that like a surety that it is not 0. Every instrument has a detection limit which will talk about in one of the module later on very soon, that it will only go up to the detection limit and when you go closer to the detection limit the reliability of the machine goes down. So, we need we need to be careful with that too.

So, now since we have good machines with low detection limit we could go down from 50 micrograms to the 10 micrograms, but we cannot really have it as 0, our goal will have to 0, but we cannot measure 0 so, that is 1 problem. The other is when you go for this lower and lower drinking water standard your cost of treatment goes up, because it becomes very difficult its get difficult to treat water at a very low at very low contaminating concentration you need some of the very advanced treatment techniques. So, when you go for advanced treatment technics it is costly. So, at again any economy you look at any company you look any country you look at any city you look at everybody has titled budget. So, all though we may say that we would like to have 0 arsenic, but first of all we cannot measure 0. So, even if you say we bring it down to the say if the detection limit is 3 micrograms per litter.

Even if you want to bring it down to three micrograms per litter just to take it from 10 to 3 the cost will be very high and that may not be worth it because of its in terms of we need we need money to do other things as well. So, that is why we have stick with productive exposure of one at acceptable rest of one in a million. So, that is what we are working with that, for the non cancer risk we use the term reference dose. Reference does typically expressed in milligram per kilogram per day which is the milligram of chemical per kilogram of the body weight and exposure in a day.

(Refer Slide Time: 15:18)



So, how we can, how we do that? We take the LOAEL and NOEAL numbers if you remember from the dose response curve, we just saw we can take the NOEAL and LOEAL numbers and we can use that number which has since it came from the animal studies we need to extrapolate that. So, we use a series of one census factors. So, multiplied by several uncertainty factors and then we take it from say mice to the human bodies and so these are because of unknown such as difference in species exposure duration and all that.

(Refer Slide Time: 16:07)



So, we use RfD is which is a reference dose some examples of RfD for example, cadmium this is oral RfD is 5 times 10 to the power of minus 4 milligram per kilogram per day. That is through the water injection and from the food its 1 times 0 to the power of minus 3 milligram kilogram per day through the food. So, what does it mean our water should be have less than whatever the water we consume it assuming 2 litters of water we consume per day. The amount of cadmium that goes into our body through 2 litters of water should not exceed this and whatever we eat per day it should not exceed this number there is no in relation in RfD for cadmium and the reason for that is there is when you try to inhale the cadmium is not volatile in a normal environmental scenario. So, that is why you do not see cadmium in relation RfD had it been certain other chemicals especially organic chemicals, most of the toxicants these kind of data the RfD data is already been done.

You can find those data out there the different websites the different databases this particular source you can go to e p a dot gov slash iris and they have the database for most of the toxicants that we come across from day today life where they have this RfD numbers in relation oral and others as well as other values of there.

(Refer Slide Time: 17:54)



So, that is, it is in terms of the cadmium concentration, then in terms of for non for the non carcinogen it is we use it for the, we use what is known as the slope factor for sorry for the non carcinogens.

We use the RfDs for carcinogen we use the slope factor slope factor is the again the unit of population affected per milligram per kilogram day.

(Refer Slide Time: 18:15)



So, that is the fraction of population affected per milligram per kilogram. Uncertainty factors again is applied over here and I will take some examples of that then, how we extrapolate this slope factor? The question is if you remember earlier will we had this data where we had this data points where we you have few data points. Now this is what you get from the epidemiological study sometimes the lab study also shows you that tension is happening at a very high concentration level and there are exposure is up to this level at 10 to the power of minus four excess conserves in our acceptable is 10 to the power of minus 6 is 1 in a million.

(Refer Slide Time: 18:24)



So, but here we are having 10 to the power of minus 4, which is more than 100 million. So, that is where we see that impacts showing up. Now this is the impact what would is shown up as part of the people having cancer or the. So, how to extrapolate this values at the lower concern lower exposure level 1 aspect could be that you can say that our make it linear.

So, there could be a linear extrapolation where things are extrapolated linearly and then that is your you make best with line and take it all the way to the x axis and then the 1 is your this is linear extrapolation 1 aspect is where the chemical is more potent at lower concentration, because we do not know, we do not know what will what is the chemical whether it is a more potent at lower concentration or less potent at lower concentration. If it is more potent at lower concentration, we will follow this top line over here. If you see this dotted line and matching with that this means that at lower concentration the effect is more it is more potent or it could be effect is less at the lower concentration that dead line will go something like that.

So, this is the different way to look at in terms of the extrapolation of epidemiological data at the lower level to find out what is the safe level, because what we are interested is 1 million cancer risk. So, we want if we draw a straight line from here we are looking at this if it is linear we are looking at a exposure level here and if you say there is an imaginary line going through this if, it is a more potent at lower way we are looking at a

exposure level over here and if it is a less potent we are looking at exposure level somewhere over here. So, based on what assumption we make the exposure level varies a lot, but if you make a in the liner 1 comes out to the somewhere somewhat in between. So, that is how. So, we have to decide and this decision is made based on certain assumptions certain statistics and all that.

(Refer Slide Time: 20:49)



So, the how we assess the risk which we are talking about in the earlier module. The first module of this particular week the toxicity we take the toxicity information along with the duration and frequency and then we find out how much risk it has in terms of the contaminated soil and also that can be used to set the protective limits.

(Refer Slide Time: 21:09)



So, here are some examples we were the how the equations for drinking water standard. So, what ultimately what we are interested in with all these toxicity information what we want is we want to come up with the safe level in our water, in our air, in our soil. So, this is 1 example of how those safe level is calculated. So, if you have to calculate drinking water standard for a carcinogen. So, we the here C is our drinking water standard and TR is the target cancer risk which is 1 in a million. That is what typically we used BW is the body weight. Body weight in kilogram and oral cancer slope factor milligram per kilogram per day, that is our slope factor that we take and at the average water consumption rate litters per day.

So, taking these values into picture we can find out what will be the standards in terms of the milligrams per litter or micrograms per litter for drinking water. So, you say if you are looking for certain particular chemical you will you need to find out what is the oral cancer slope factor. That is the value you will get from those e p a iris websites and other sources. Other things body weight if it is an adult you can take 65 to 70 kg. There is standard of how much we take then unit this 1 cancer risk 1 in a million average water consumption rate is taken as around 2 litters per day. So, that is you can plug in those numbers and you get that.

(Refer Slide Time: 22:38)



So, that is for carcinogen for non carcinogen we as use as I told you earlier we used reference source. So, we have this oral reference dose because water will be taken orally. So, we have the oral reference dose that comes in there. Then we have the body weight, then the average water consumption. So, once you multiplied by this this is your milligram per kilogram per day you multiplied by kilograms. So, this kilogram and this kilogram will be go away then you have a litters per day. So, this day and this day will go away and then you will end up with milligrams per litter. So, that is your standard that you will see for milligrams per litter for a non carcinogen. So, that is where how this equations are calculated. So, that is what for drinking water.

(Refer Slide Time: 23:18)



Say if you think about the soil, for soil what we take clean soil standard is say if you for the carcinogen is where you where you worried about the ingestion route only. Ingestion route means say if the small kids has the tendency to touch the surface of the soil and then they will take how hand in the mouth. So, that is call hand to mouth activity. So, in terms of the hand to mouth activity, these, this small this small kids, we can calculate because they have the lower body weight. So, we have becoming a more conservative there as well. So, again concentration in milligrams per kilogram, so that would be your target cancer risk in 1 a million body weight which we can take body weight is for a adult or for the for the small kids as the case may be.

Then you have the oral cancer slope factor this data you will get from the iris website that e p a dot gov slash iris then you have your ingestion rate which is how much for example, if they have a hand to mouth activity where they put their hand in the mouth from after touching the surface of the soil. So, at to say how much soil is getting into the body. So, that is very important in terms of calculating with. For the small kids we see a lot all those happening over there. So, that is the, our how this concentration can be calculated in terms of the clean soil standard. So, that is needed for that.

So, that is in terms of, once you have all these information you can go for what is the risk assessment in terms of the risk assessment there are four steps we talked about the basics

of risk assessment in the previous module then this, for we have given here overview of overview of the toxicology aspect the toxicant aspect.

(Refer Slide Time: 25:05)



Now, if you look at the risk assessment part of it after having all these information first off all we need to find out what is what is hazard. Hazard identification so, say if you are looking at a certain particular scenario, what is at what, what is hazard associated with that what kind of chemicals present what kind of hazard whether it then dose response. I think I gave you already a good x, I showed you dose response in the previous module and then also does response, how it is generated? In this particular modules you should have a very good idea.

So, we need to do the does response evaluation for that particular chemical. Then the exposure assessment how much exposure think about like what kind of the exposure how long the exposure and that is the important and then we have to correct raised the risk. What is risk is coming up and then when we have done all that one we have assist the risk. We can manage the risk, manage means either you reduce the level of exposure or you reduce the level of toxicant in the in your process.

So, whatever works because sometimes, something will work on the other time the other options may be work. So, it is not a 1 size fit all solutions, but this is we have after we have after looking at this 4 like four steps we can manage the risk and that is where it is very, very important and sometimes risk management also has a risk communication and

risk communication especially if you are a company risk communication is very, very critical say what happened with our with nestle Maggi issue was it was more of a risk communication of problem rather than a risk like, risk from those particular product of course, there was risk from that heavy metals found in there, but heavy metals can be there in other products too.

If you look at I if you take some like our soil our food samples you go to any of the mall or any of the corona stores and take some food samples and send it to an independent lab you will find lot of elevated level of certain contaminants there in our food. Reason is the food, is it is not the food, it is the water and the soil. Our water is contaminated, our soil is getting contaminated our water it is for most part contaminated to certain extend and we have air pollution is use in many parts of the country. So, all these things add up to having these things been toxic. So, that is why it is uses as at the Nestle Maggi issue was more of the risk management problem rather than a risk sorry this risk a communication problem, rather than a risk assessment or risk management problem.

(Refer Slide Time: 27:49)



So, risk assessment, it provides a qualitative and quantitative estimation of the likelihood of adverse effect that may result from exposure to specific health hazards or from the absence of beneficial influences. So, that is how we look at qualitative as well as the quantitative estimation is done. (Refer Slide Time: 28:05)



Risk management is after you characterize the risk as mentioned in 2 slides back you seek to control the exposure of toxic chemicals in the environment that leads to law and policy. That leads to how much should be the exposure level a standards how much the shah occupational health and safety issues. So, that is how its leads to those laws as well as the policy aspect of that.

(Refer Slide Time: 28:29)



So, based on, so, this is how kind of again tend to summarize you are relationship between the toxicological parameters risk assessments, they how the risk assessment should be done and also in terms of the risk communication. Risk communication is very very important say if you are working in a particular setting where any anywhere you work there will be some risk even driving to the place of driving to your place of work has some risk involve if you are using a 2 wheeler or four wheeler that is again there is a risk associate and then the car seems to be must safer, but then car also has there is a level of risk involved there as well. So, as long as in any setting that you have there will be some risk involve you need to identify the risk you need to manage the risk and you need to communicate the risk very well to your employees or to your stake holders a first.

And of course, in today's world given to the entire like a global community through either through press meets and them. So, with that we will try to kind of conclude this particular module and then in the next module we will try to get into some of the examples of some of the important chemicals. So, which is being used into the environment which is getting released into the environment and what are issues associated with that. So, let us conclude this particular module.

Thank you very much and again I will see you in the next module. All the best.