

# DERIVATION OF FOOD SAFETY STANDARDS

[ 1 ]

**ACTION LEVEL**



# ACTION LEVEL

US Food And Drug Administration (US-FDA)

**ACTION LEVELS** are established based on the UNAVOIDABILITY of poisonous or deleterious substances and DO NOT represent permissible levels of contamination where it is avoidable

**ACTION LEVEL** represents limit at or above which FDA will take legal action to remove product from market



**The blending of food or feed containing a substance in excess of an action level with another food or feed is not permitted, and the final product resulting from blending is unlawful, regardless of the level of contaminant**

**DILUTION DOES NOT WORK!**

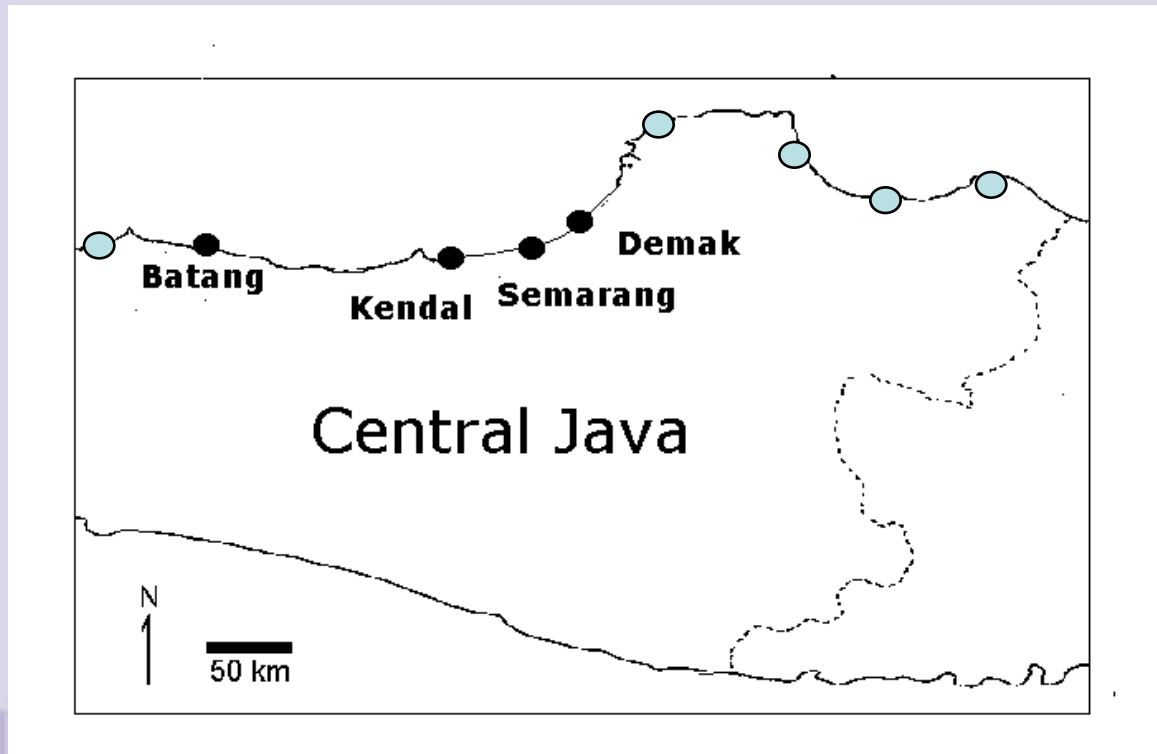
**Where no established action level exists, FDA may take legal action against the product at the minimal detectable level of the contaminant**

For a detailed list, see US-FDA,  
Industry Activities Staff Booklet,  
March 1998 ([www.fda.gov](http://www.fda.gov))



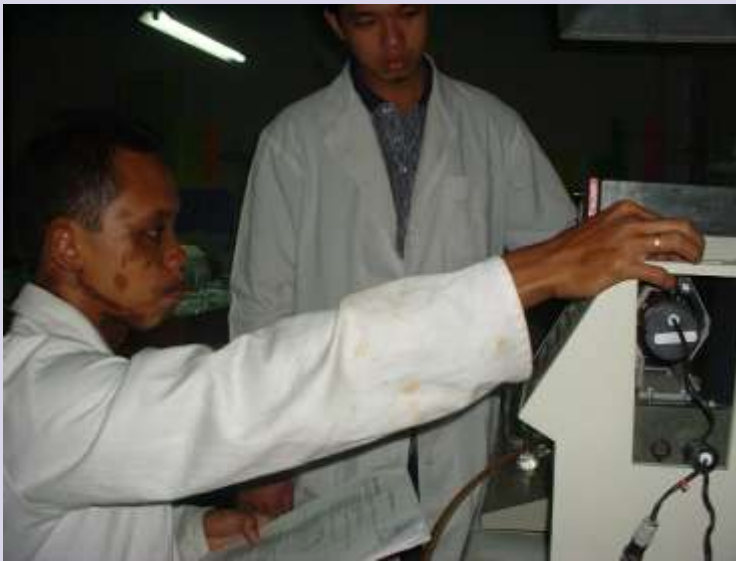
# HOW TO DERIVE ACTION LEVEL (1)

Sampling of subjective foodstuff across the geographical boundary **SPATIAL DISTRIBUTION ENCOMPASING ALL LEVELS OF CONTAMINATION**



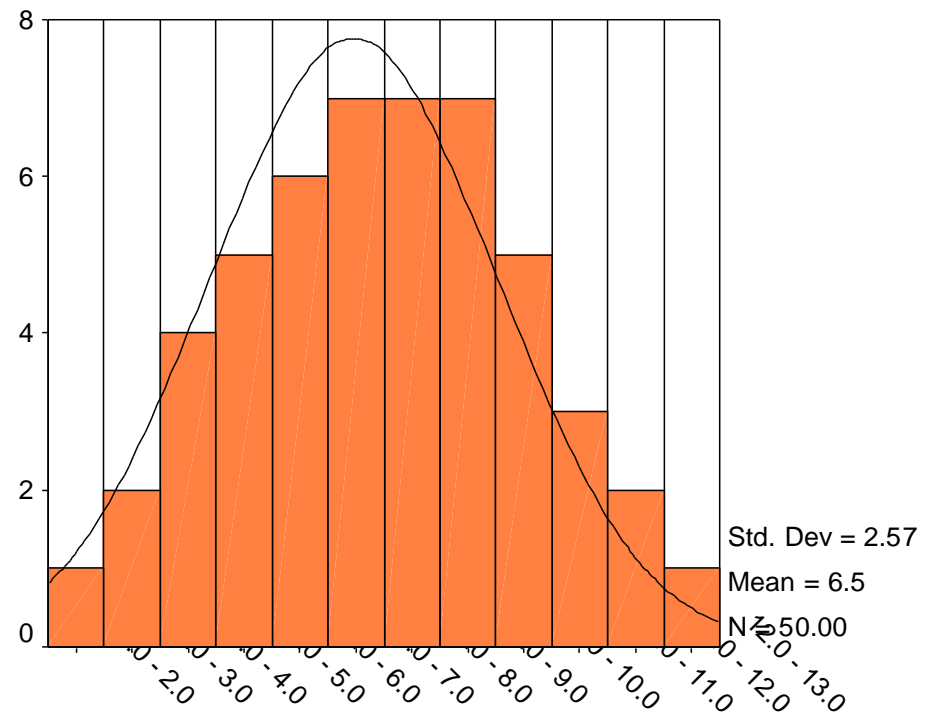
# HOW TO DERIVE ACTION LEVEL (2)

Determination of concentrations of toxicant or contaminant in the sample of foodstuff



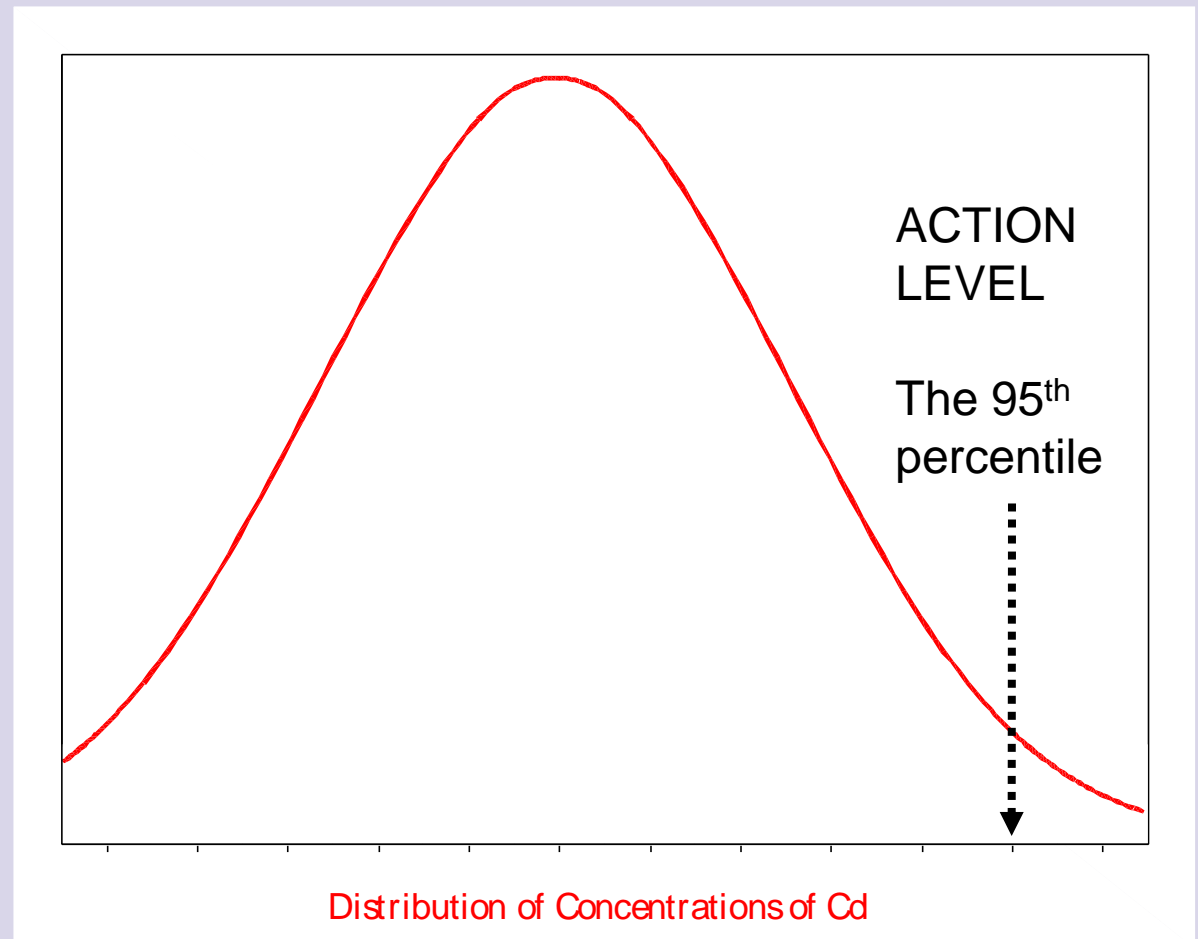
# HOW TO DERIVE ACTION LEVEL (3)

Set-up a distribution based on values (data) of contaminant concentration



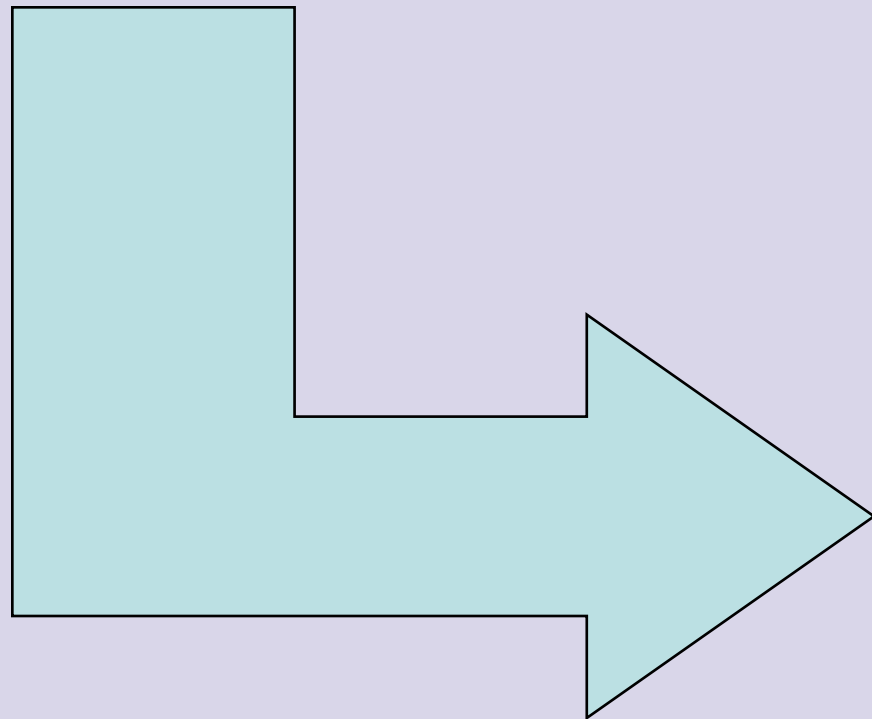
# HOW TO DERIVE ACTION LEVEL (4)

Identify the safety limit based on the  $X^{\text{th}}$  percentile (the 90<sup>th</sup> or 95<sup>th</sup> percentile) of the distribution

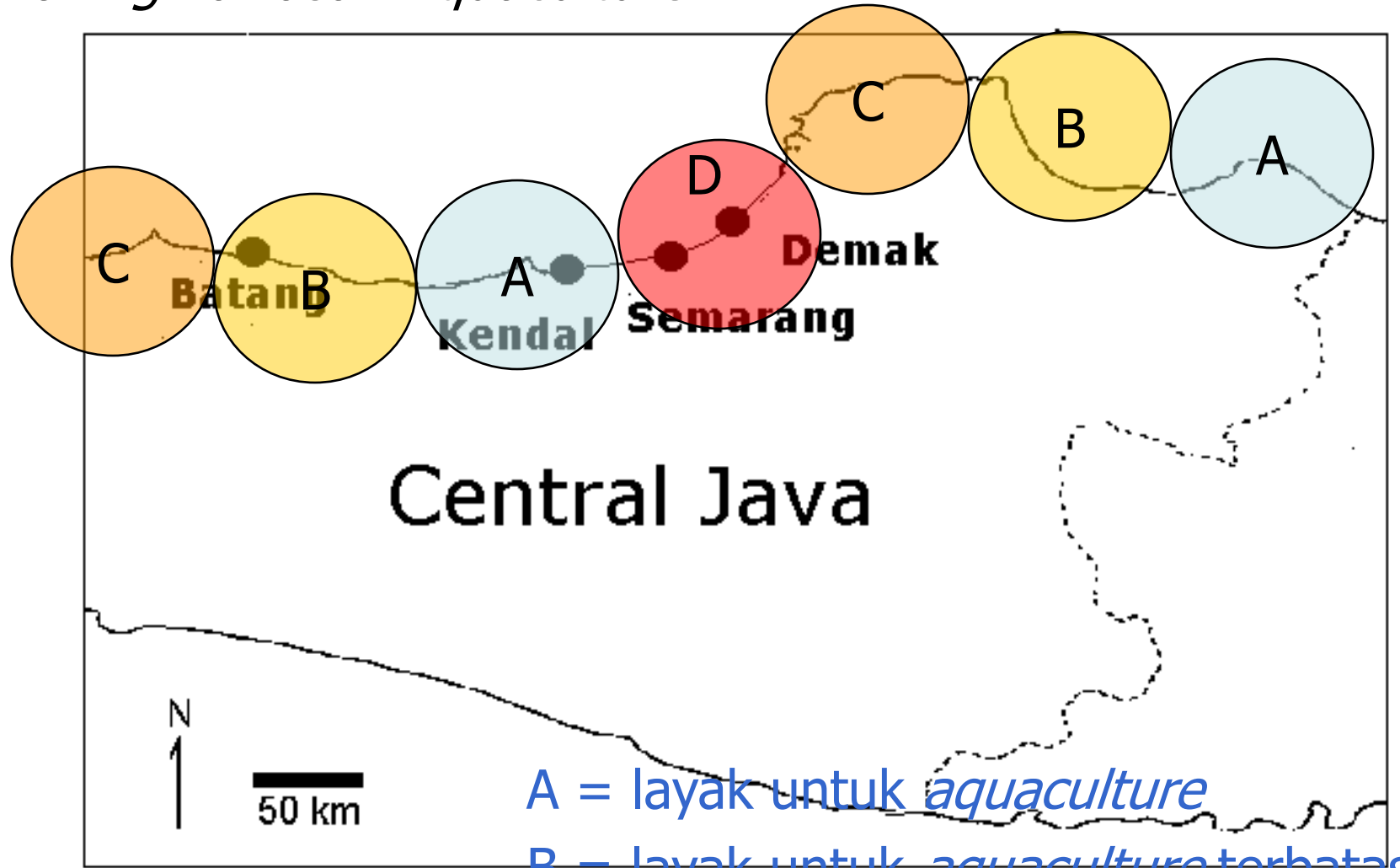




# APPLICATION



# Zoning Kawasan *Aquaculture*



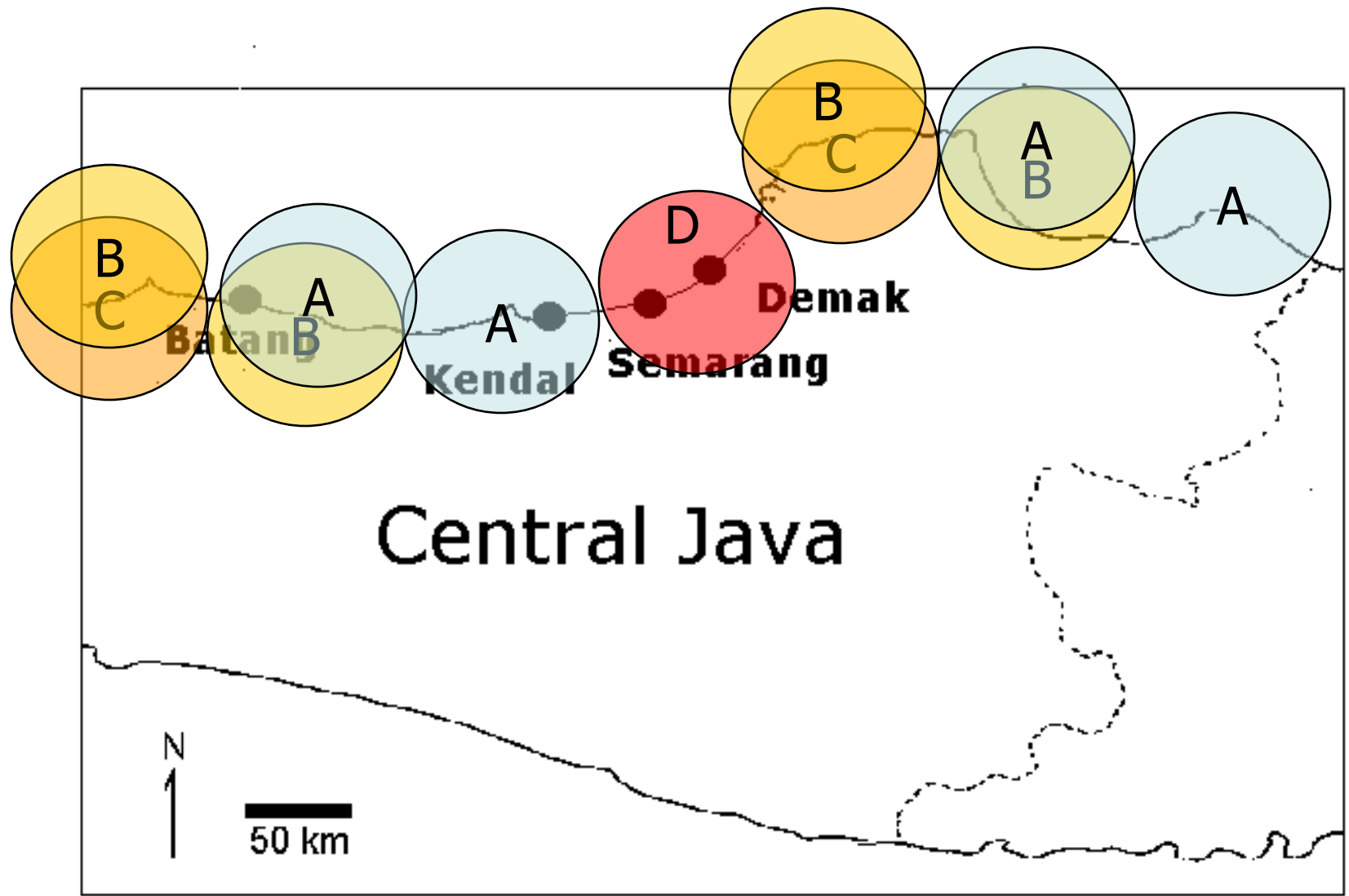
A = layak untuk *aquaculture*

B = layak untuk *aquaculture* terbatas

C = tidak layak untuk *aquaculture*

D = sangat tidak layak untuk *aquaculture*





*Zoning Kawasan Aquaculture*



5:

	location	cd	var	var	var	va
1	1	2.00				
2	2	2.10				
3	3	2.10				
4	4	2.20				
5	5	2.20				
6	6	2.20				
7	7	2.30				
8	8	2.30				
9	9	2.30				
10	10	2.30				
11	11	2.40				
12	12	2.40				
13	13	2.40				
14	14	2.40				
15	15	2.40				
16	16	2.50				
17	17	2.50				
18	18	2.50				
19	19	2.50				
20	20	2.50				
21	21	2.50				
22	22	2.60				
23	23	2.60				
24	24	2.60				
25	25	2.60				
26	26	2.60				
27	27	2.70				
28	28	2.70				
29	29	2.70				
30	30	2.70				





5:

	location	cd
1	1	2.0
2	2	2.1
3	3	2.1
4	4	2.2
5	5	2.2
6	6	2.2
7	7	2.3
8	8	2.3
9	9	2.3
10	10	2.3
11	11	2.4

- Reports ▶
- Descriptive Statistics ▶**
  - Frequencies...**
  - Descriptives...
  - Explore...
  - Crosstabs...
- Custom Tables ▶
- Compare Means ▶
- General Linear Model ▶
- Correlate ▶
- Regression ▶
- Loglinear ▶
- Classify ▶
- Data Reduction ▶
- Scale ▶
- Nonparametric Tests ▶
- Time Series ▶
- Survival ▶
- Multiple Response ▶
- Missing Value Analysis...



5:

## Frequencies: Statistics

## Percentile Values

- Quartiles
- Cut points for  equal groups
- Percentile(s):

Add

95

Change

Remove

## Central Tendency

- Mean
- Median
- Mode
- Sum

Continue

Cancel

Help

- Values are group midpoints

## Dispersion

- Std. deviation     Minimum
- Variance             Maximum
- Range                 S.E. mean

## Distribution

- Skewness
- Kurtosis

16

16

2.50



FOODSAFETY.sav - SPSS Data Editor

File Edit View Data Transform Analyze Graphs Utilities Window Help



5:

	location	cd	var	var	var	var	var
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15	15	2.40					

**Frequencies: Charts**

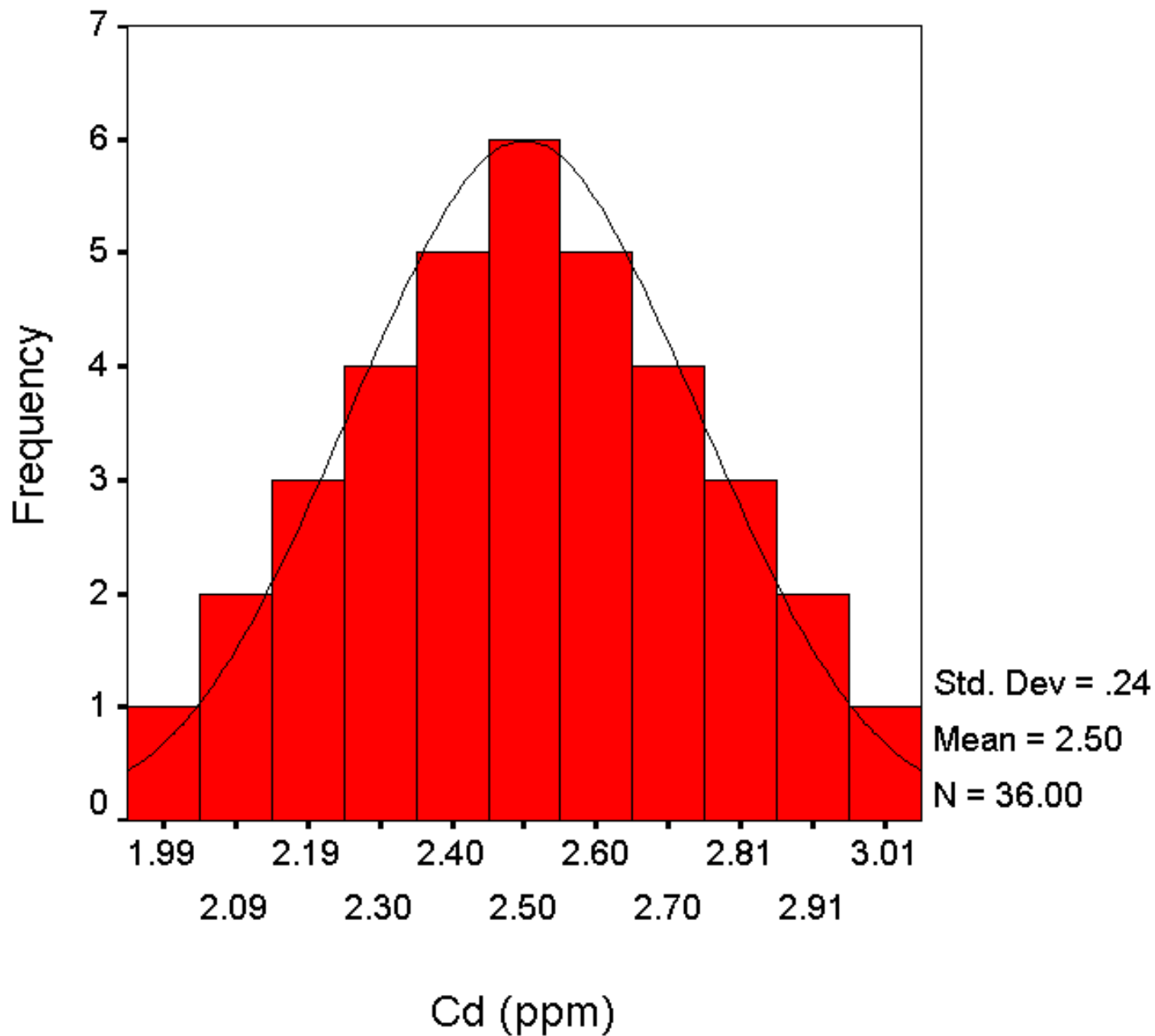
Chart Type

- None
- Bar charts
- Pie charts
- Histograms
  - With normal curve

Chart Values

- Frequencies
- Percentages

Buttons: Continue, Cancel, Help, OK, Paste, Reset, Cancel, Help





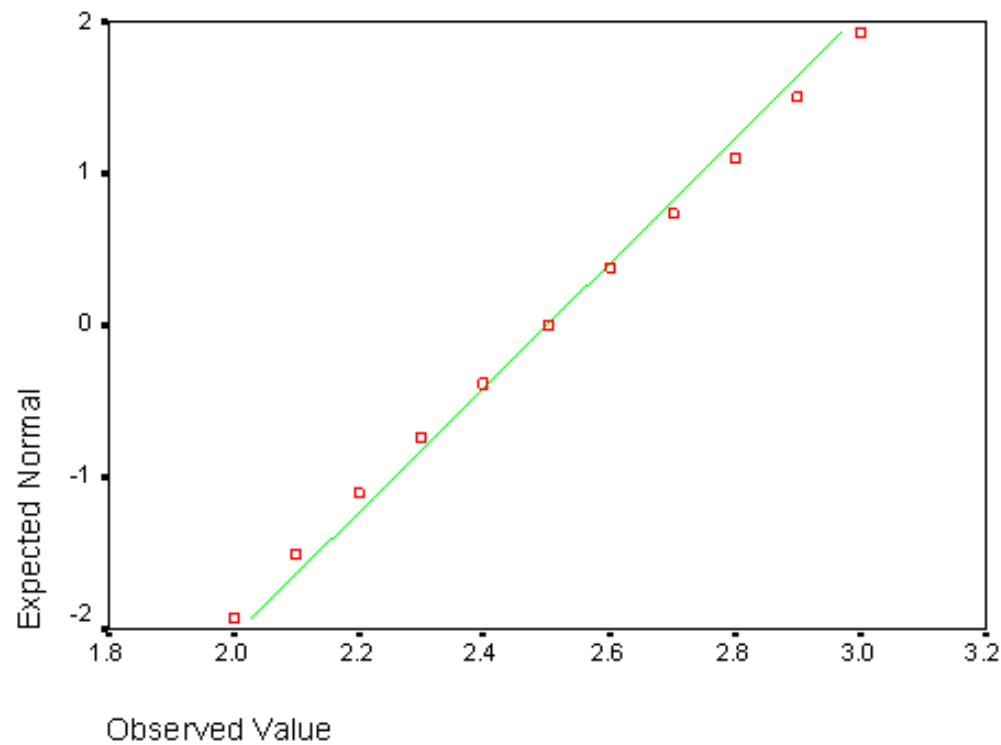
	Kolmogorov-Smirnov <sup>a</sup>			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
CD	.083	36	.200*	.977	36	.705

\*. This is a lower bound of the true significance.

a. Lilliefors Significance Correction

**CD**

Normal Q-Q Plot of CD



### Descriptives

			Statistic	Std. Error
CD	Mean		2.5000	4.082E-02
	95% Confidence Interval for Mean	Lower Bound	2.4171	
		Upper Bound	2.5829	
	5% Trimmed Mean		2.5000	
	Median		2.5000	
	Variance		6.000E-02	
	Std. Deviation		.2449	
	Minimum		2.00	
	Maximum		3.00	
	Range		1.00	
	Interquartile Range		.4000	
	Skewness		.000	.393
	Kurtosis		-.545	.768

### Percentiles

		Percentiles						
		5	10	25	50	75	90	95
Weighted Average(Definition 1)	CD	2.0850	2.1700	2.3000	2.5000	2.7000	2.8300	2.9150
Tukey's Hinges	CD			2.3000	2.5000	2.7000		



[ 2 ]

# MAXIMUM RESIDUE LIMIT (MRL)

# **MAXIMUM RESIDUE LIMIT**

(FAO, WHO, ASEAN, Badan POM etc)

## **UNIT**

**mg toxic substance per kg food item**

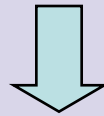
## **CALCULATION**

- **Acceptable Daily Intake (ADI) of the toxic substance**
- **Consumption of selected food item**

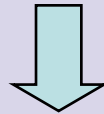


## NOAEL/NEL/NOEC

Toxicological Database: results of toxicity tests  
(human or other mammals)



Application of a safety factor – usually 100  
(a “quick and dirty” method)



Acceptable Daily Intake (ADI) or Reference Dose (RfD)

**NOAEL = no observed adverse effect level**

**NEL = no effect level**

**NOEC = no observed effect level**



## EXAMPLE:

### Estimation of MRL of toxic substance “X” in rice

- **ADI** of toxic substance “X” = 10 mg/kg bw
- **Daily Consumption of rice = 100 g**  
(~ 20% of total food intake)
- **Reference body weight = 60 kg**
- **Total permissible daily intake of “X” =  $60 \times 10 \text{ mg} = 600 \text{ mg}$**
- **Total permissible daily intake of “x” via rice consumption =  $20\% \times 600 \text{ mg} = 120 \text{ mg}$**
- **MRL =  $120 \text{ mg}/100 \text{ g} = 1.2 \text{ g/kg rice}$**



## EXAMPLE:

- **MRL (Cd) = 1.20 mg/kg rice**
- **Cd concentration in rice = 0.1 mg/kg**
- **Body weight of the person = 70 kg**
- **Rice comprises  $\pm 20\%$  of the total food intake of the person**
- **What is maximum permissible daily consumption of rice?**



## **Part 6. Food Safety in Retail Foods**

26. Commercial Food Service Establishments: The Principles of Modern Food Hygiene .....	455
27. Institutional Food Service Operations .....	523
28. Food Service at Temporary Events and Casual Public Gatherings .....	549

## **Part 7. Diet, Health, and Food Safety**

29. Medical Foods .....	573
30. Food Fortification .....	607
31. Sports Nutrition .....	627
32. Dietary Supplements .....	641
33. Functional Foods and Nutraceuticals .....	673



## **Part 5. Food Safety Operations in Food Processing, Handling, and Distribution**

21. Food Plant Sanitation .....	383
22. Food Safety Control Systems in Food Processing .....	403
23. Food Safety and Innovative Food Packaging .....	411
24. Safe Handling of Fresh-Cut Produce and Salads .....	425
25. Good Manufacturing Practices: Prerequisites for Food Safety .....	443

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# PowerPoint Presentations

Kelas B

FOOD FORTIFICATION

MEDICAL FOOD

INNOVATIVE FOOD PACKAGING

INSTITUTIONAL FOOD SERVICE

Kelas A

DIETARY SUPPLEMENT

HANDLING OF FRESH CUT PRODUCE

FOOD SAFETY CONTROL SYSTEM

INNOVATIVE PACKAGING

