Technical Symposium of
The International Zinc Association - Southern Africa (IZASA)
in Collaboration with
The Fertilizer Society of South Africa (FSSA)

16August 2007,
CSIR Convention Centre, Pretoria

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Fertilization to Fortification: The Role of Zinc in Human Nutrition

SEMINAR 2.
The Impact of the European REACH Regulations on Exporters to Europe

FSSA-MVSA

ZINC

IZASA
INTERNATIONAL ZINC ASSOCIATION OF SOUTHERN AFRICA

Why two seminars – one day?

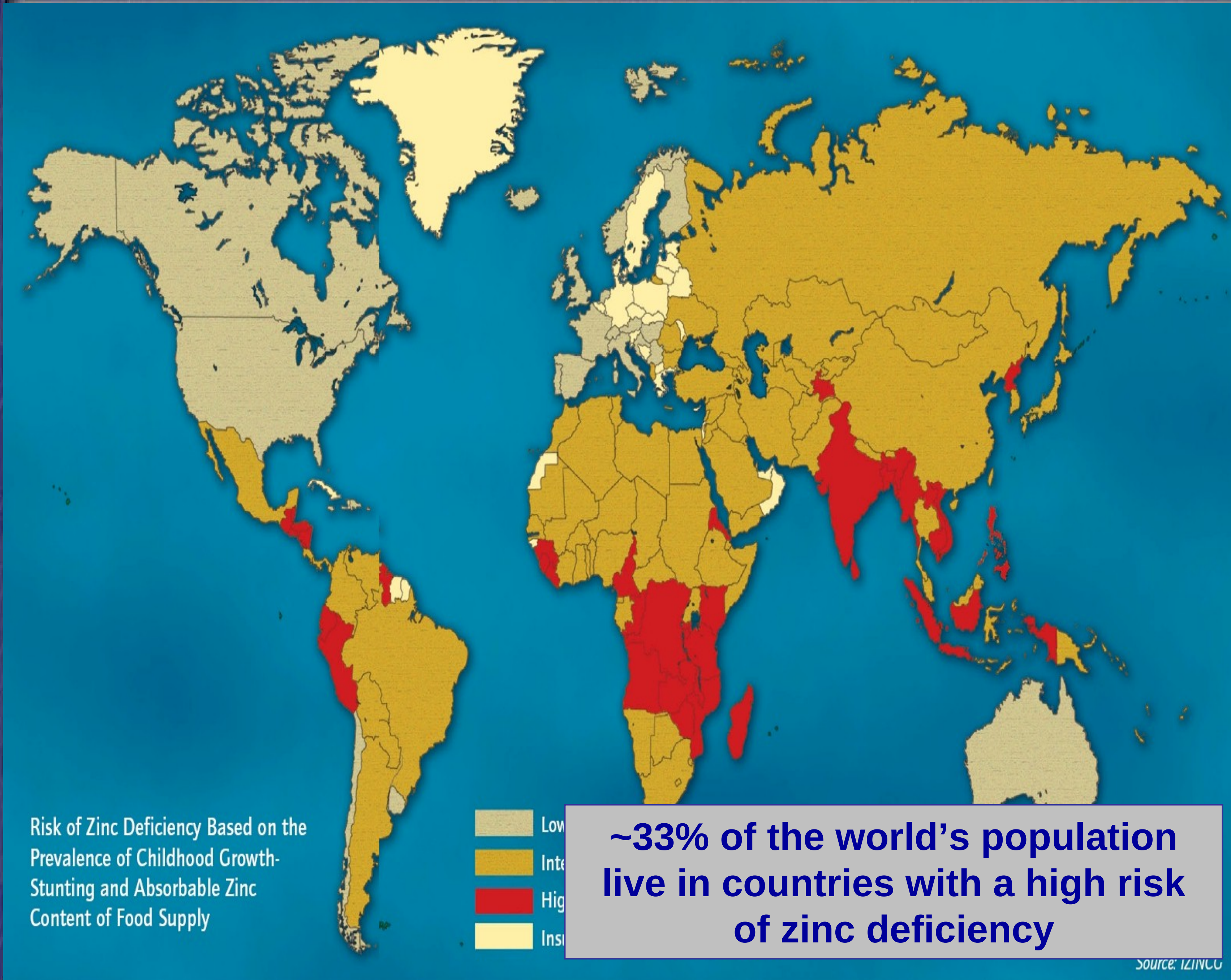
- The plant and human benefits of **zinc** are physiological
- Physiology involves **chemical** activity
- Chemical activity defines zinc's primary market – **galvanizing**
- **REACH** is the European Chemical Management system
- It will become **global**
- It will impact **ALL chemicals**

ZINC

www.ZincWorld.org

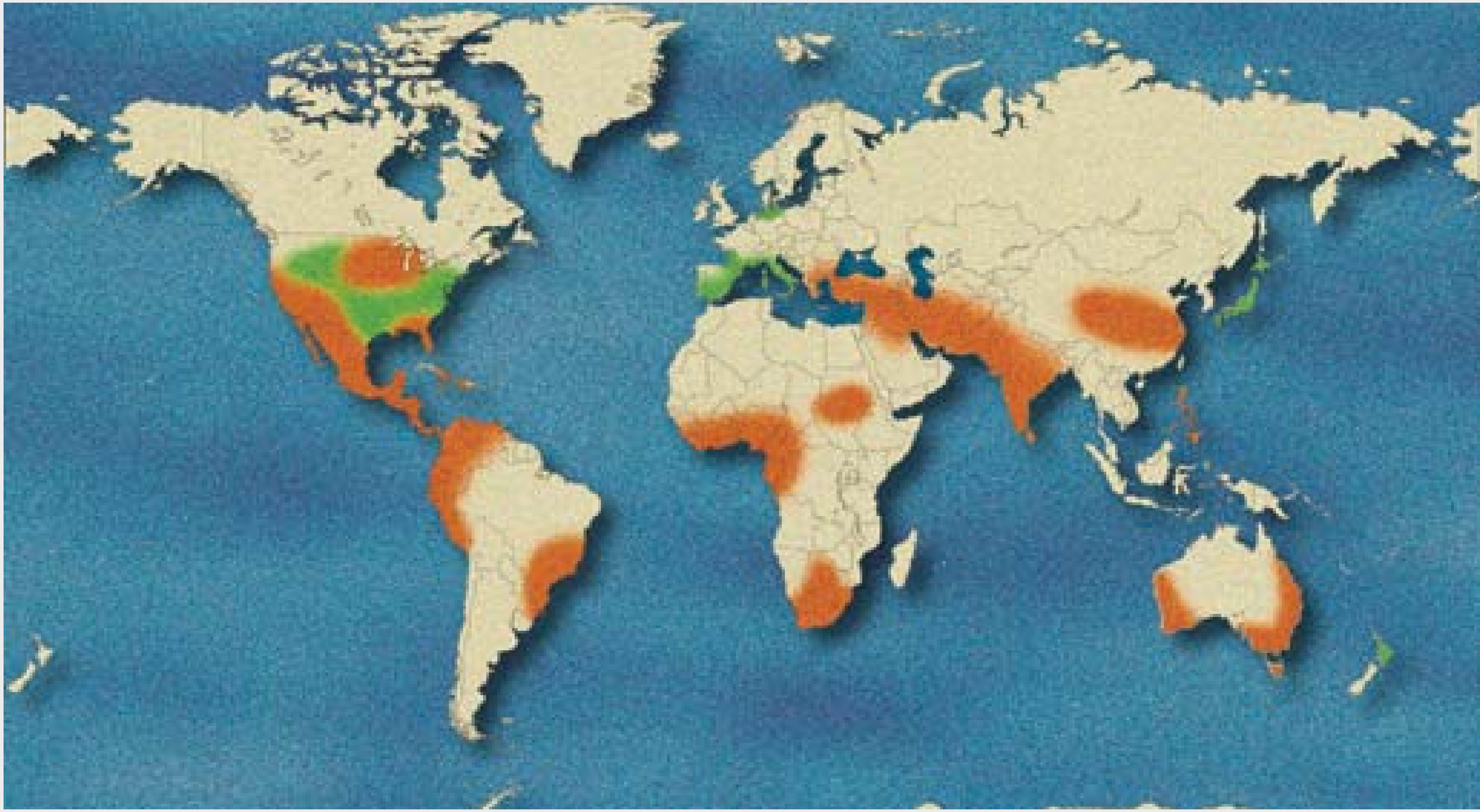
International Zinc Association

www.ZincWorld.org



~33% of the world's population live in countries with a high risk of zinc deficiency

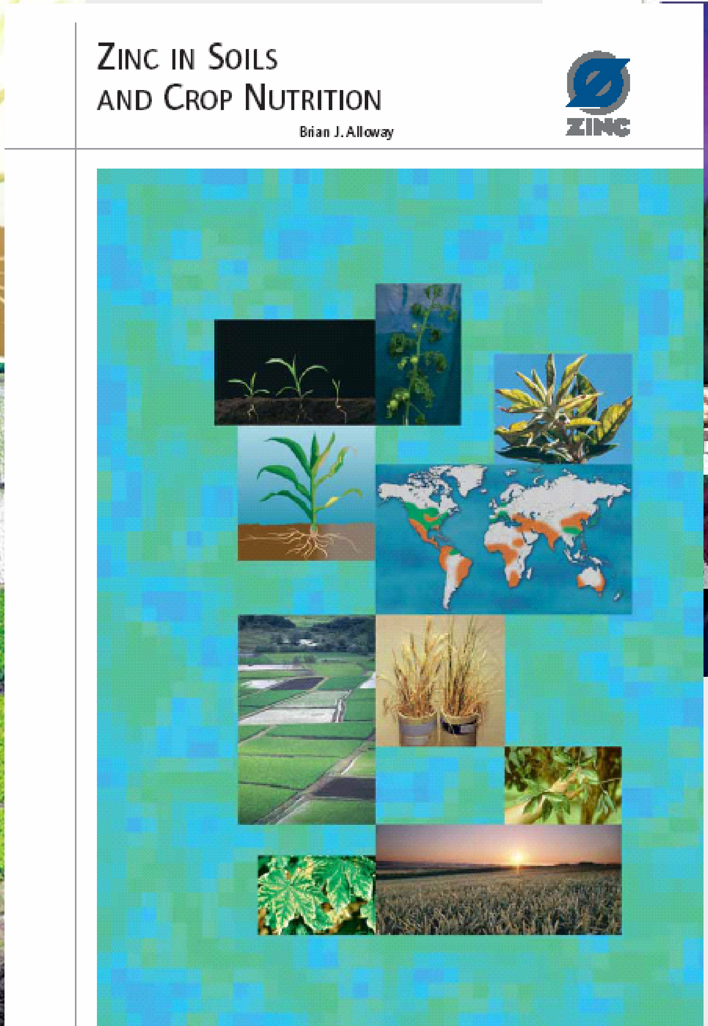
World Zinc Deficiency in Soil: Major Areas of Reported Problems



Zinc deficiency is the most common micronutrient deficiency problem

Orange = high; Green = low

Zinc's essentiality for human and crop nutrition



REACH (registration, **e**valuation and **a**uthorisation of **Chemicals) – the issue**

- Worldwide interest in **Chemicals** management promoted through the RIO declaration in 1992
- Free markets, international trade and political interest raised the profile
- The International Forum on **Chemical** Safety drove the process
- Output –
  - Global Harmonised Classification and labeling system (UN-**GHS**) – will be adopted by SA in its entirety
  - Strategic Approach to International **Chemicals** Management

ZINC

Why is it so important for metals?

- Industry supports the principle of responsible care
- **REACH** offers opportunity to harmonize assessment of chemicals and products in EU & WW (**GHS** implementation)
- Will halt unscientific unfriendly initiatives towards metals
- Determines assessment methodology and database for all major environmental policies

REACH

Workers legislation

Product legislation

Water, groundwater, soil

CONSUMER LEGISLATION

Recycling programmes

Why is REACH important to you?

- **All exporters**, exporting to the **EU** will have to comply with **REACH**
- **Non-compliance means denied market access** to the EU
- The **legislation is in place** and the clock is ticking
- An example – if you export an article (≥ 1 t/y) and if the **substance is intended to be released** under normal or reasonably foreseeable conditions of use **it shall be registered** – no maybe!

www.ZincWorld.org

Enjoy the day and ask YOUR questions!

ZINC

NEIL MILES

Resumé

Neil Miles currently manages the Analytical Services, Biochemistry and Biometry Sections of the KwaZulu-Natal Department of Agriculture and Environmental Affairs at Cedara.

He trained as a soil scientist at the University of Natal. His PhD thesis was on “Pasture Responses to Lime and Phosphorus on Acid Soils in Natal”.

Neil is actively involved in research and extension, with his particular interests being soil health and the nutrition of high-yielding pastures. He has published widely in both scientific journals and the popular press on these subjects.

FOOD SECURITY IN SUB-SAHARAN AFRICA – THE ROLE OF FERTILIZERS

Dr Neil Miles

KZN Dept. of Agric. & Environmental Affairs

Acknowledgements: **Alan Manson, Siegfried Haschke, Guy Thibaud, Vic Roberts, Bright Mashiyana, Neil Baxter**

This Presentation

1. **How is <u>Sub-Saharan Africa</u> measuring-up in terms of food production ?**

2. **<u>South Africa</u>:**

   - food security strategies

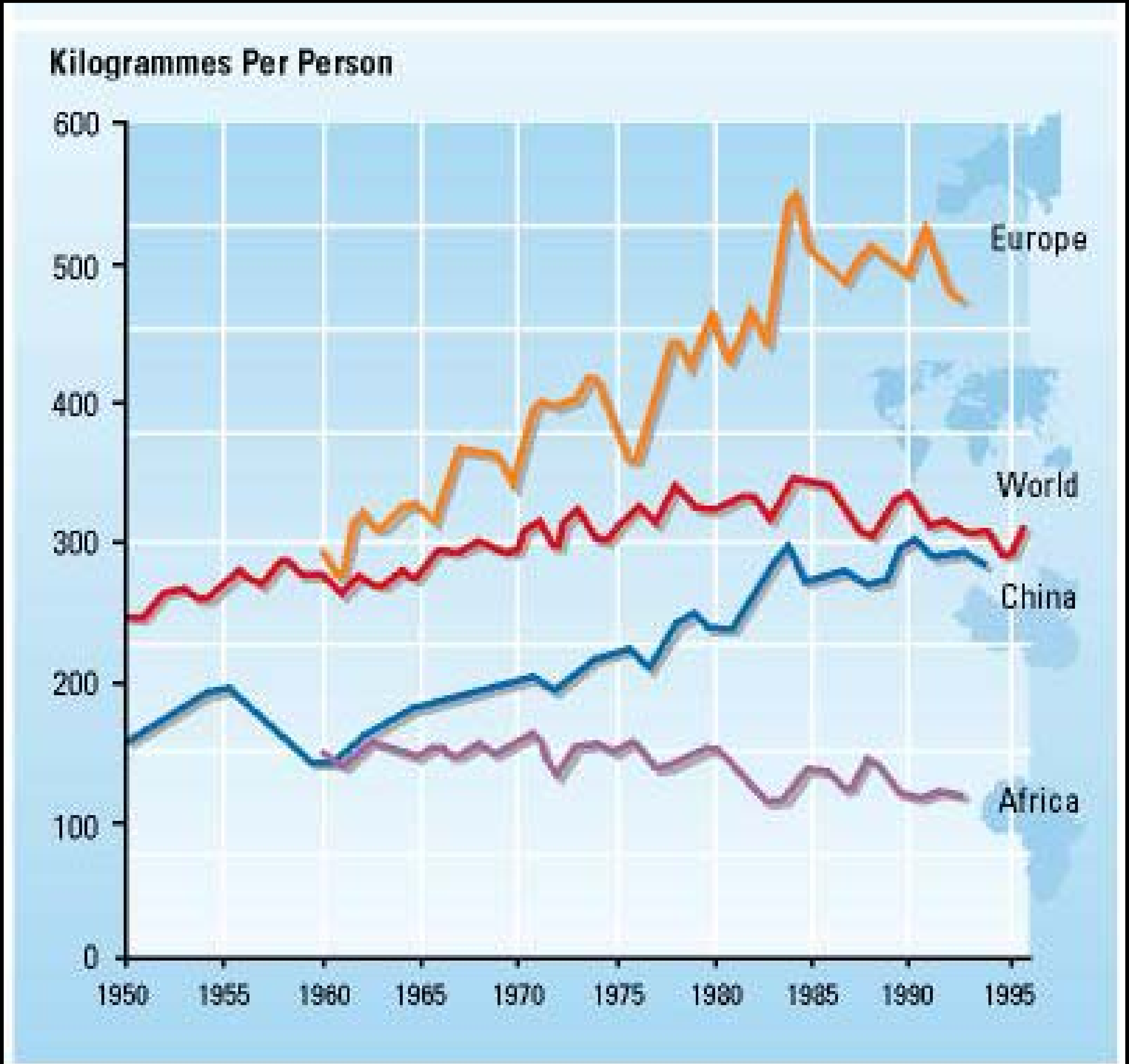
   - household vs national food security

   - farming systems and fertilizers

Food production in Sub-Saharan Africa ?

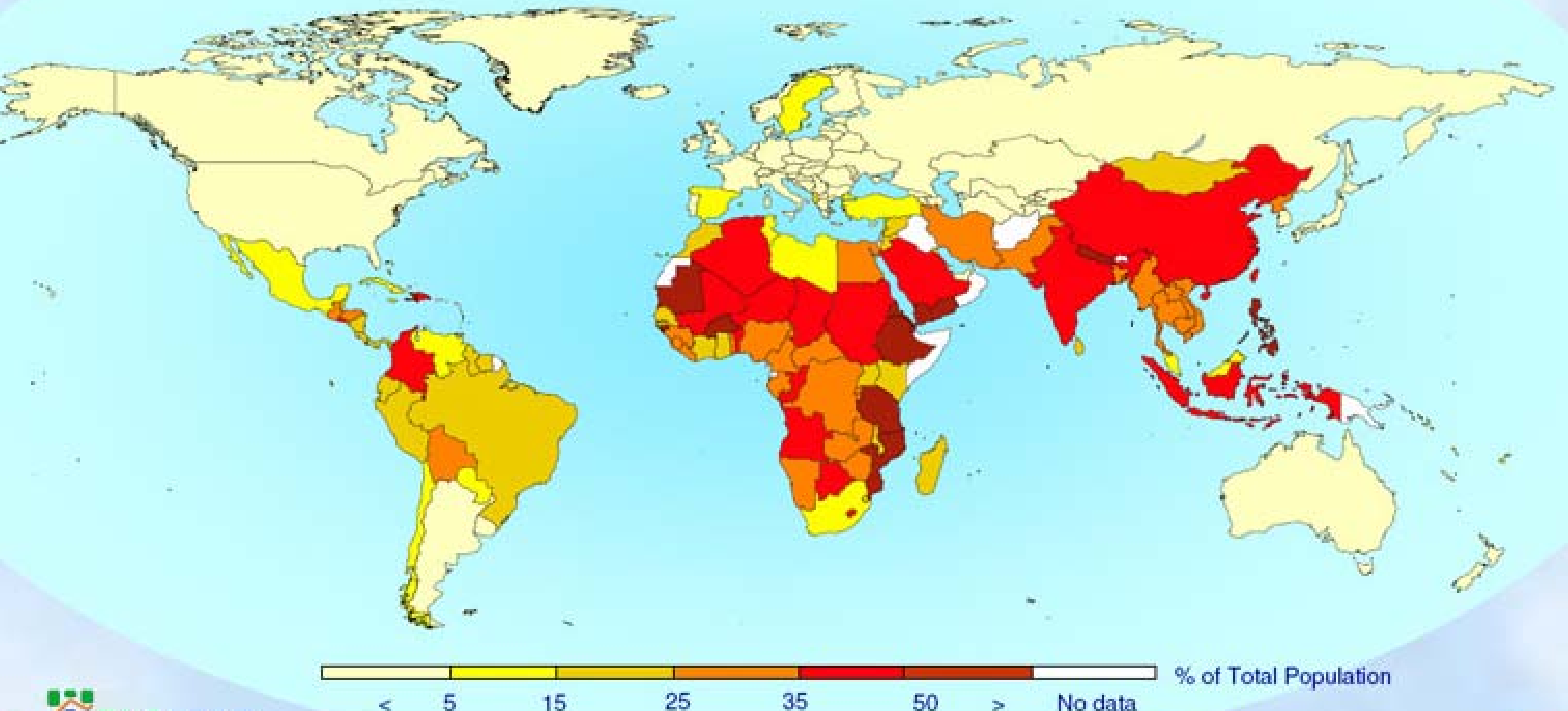
Grain production for the world and selected regions

Worldwatch Institute, 1996



Undernourished population

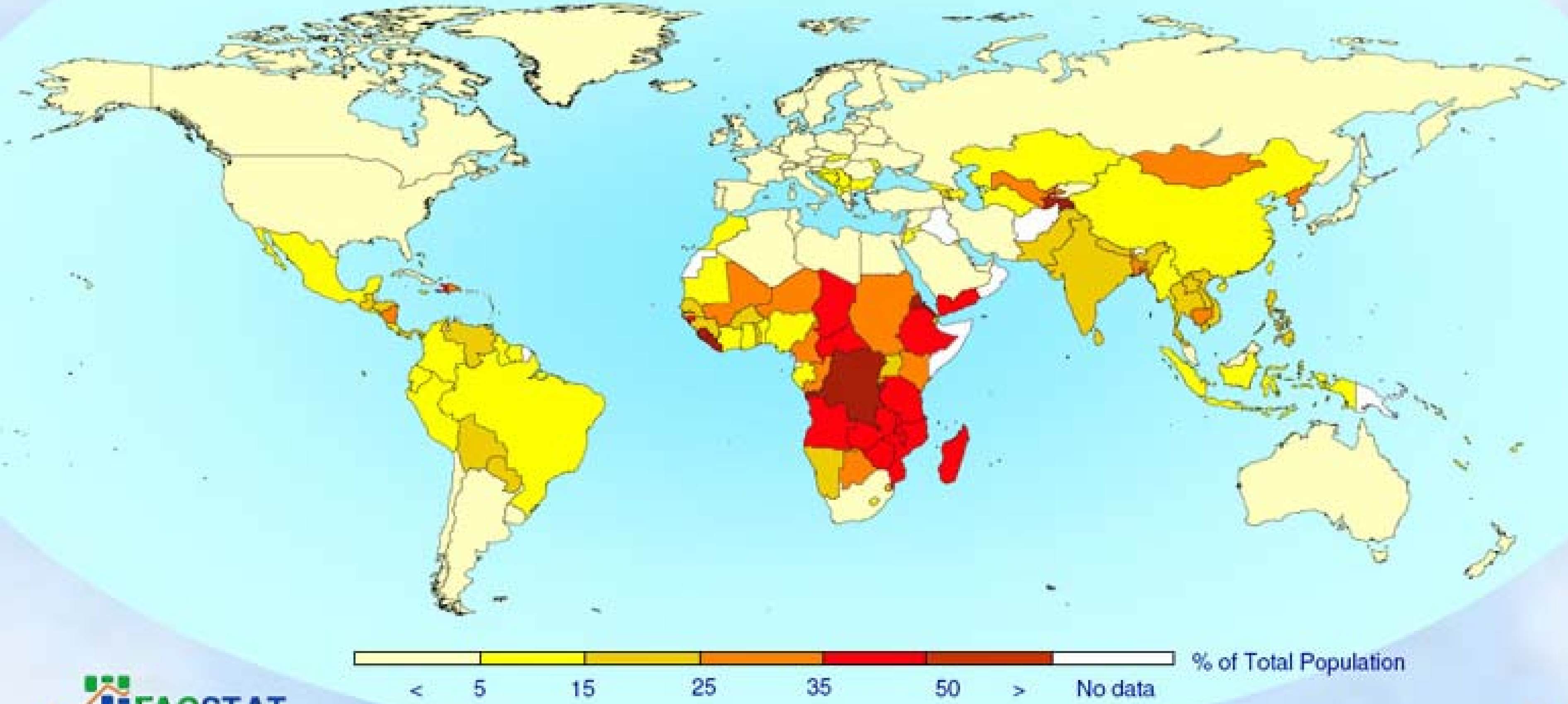
1970



FAOSTAT

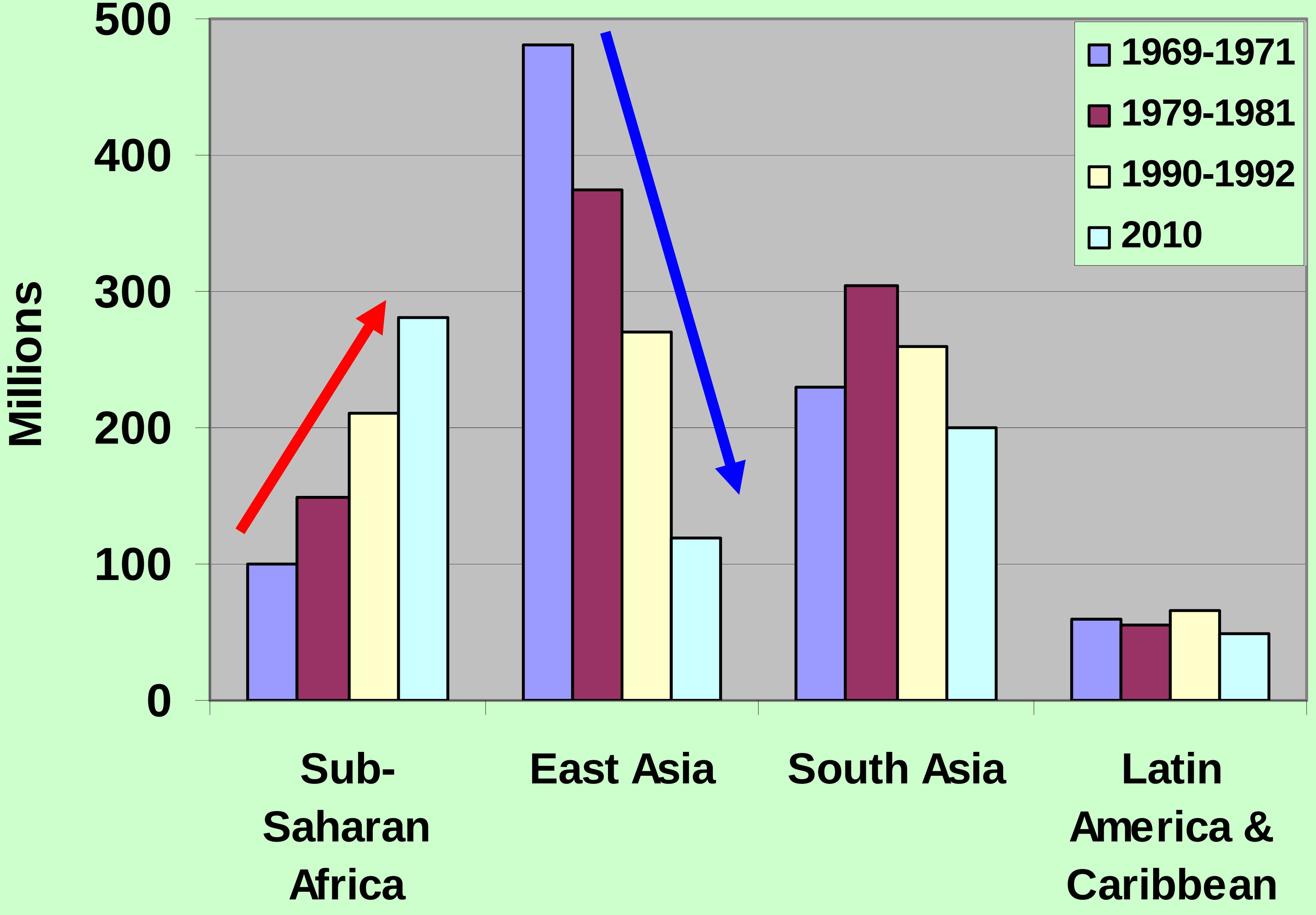
Undernourished population

2003



FAOSTAT

Number of persons chronically undernourished in developing countries



Current developments….

- Lesotho: 30% of population facing starvation
- Zimbabwe.

Overwhelming evidence that sub-Saharan Africa is widely <u>food-insecure</u>, and predictions are that this situation will <u>deteriorate further</u>

Where are we going wrong ?

South Africa: Key strategic questions we should be asking….

1. **HOW MANY PEOPLE** will we need to feed in 2010, 2015, 2020 …… ?
2. **WHERE** will they be **LOCATED** (rural, urban)?
3. **WHERE** will the food be **SOURCED** ?
4. **HOW** will it be **PRODUCED** ?

South Africa: Key strategic questions we should be asking….

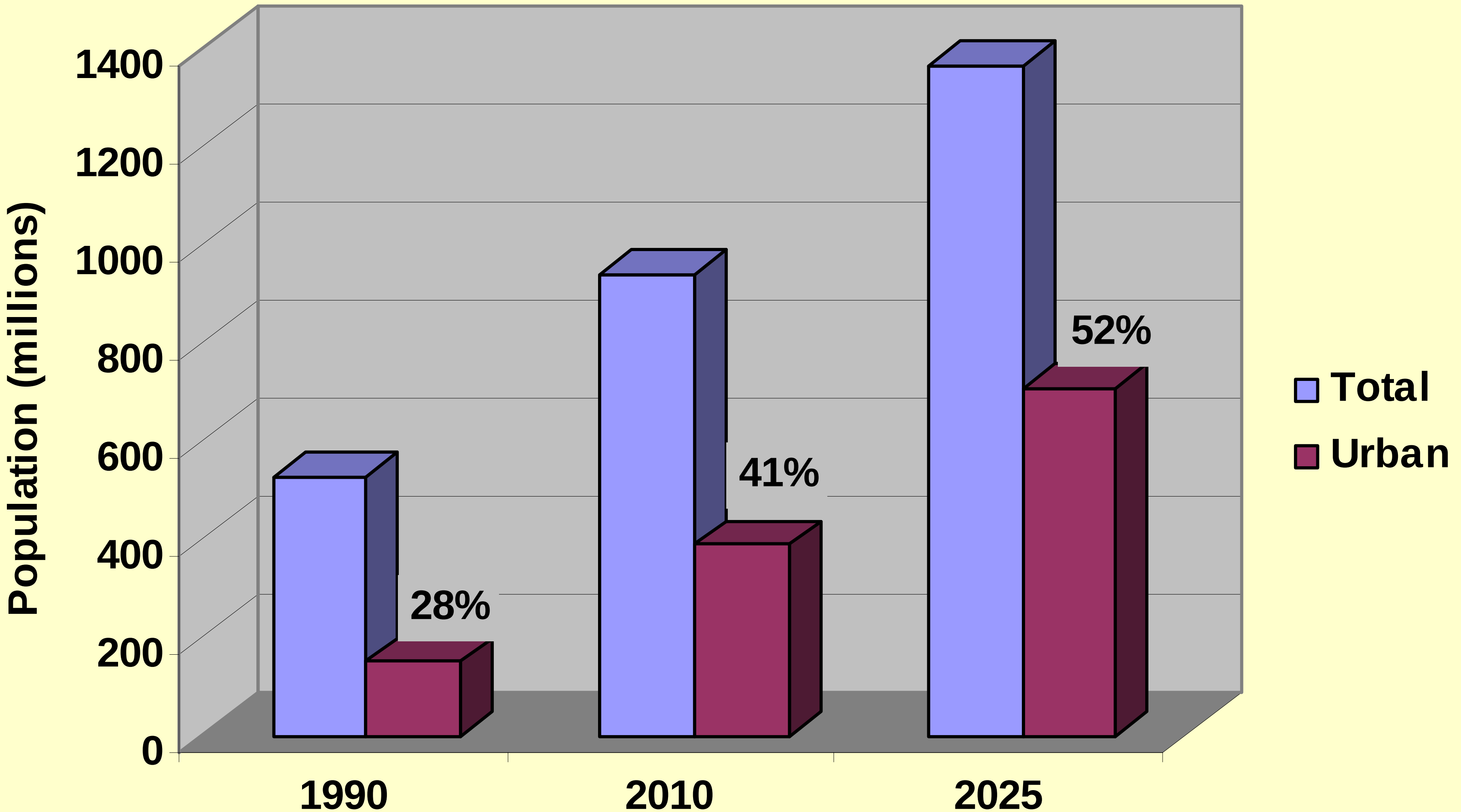
1. HOW MANY PEOPLE will we need to feed in 2010, 2015, 2020 …… ?

2. WHERE will they be LOCATED ?

<u>Sub-Saharan Africa's demographics - the reality</u>…..

The highest rates of urbanization in the world .

Urbanization in Sub-Saharan Africa



UNCED, 1995

- **By 2025, the majority of the poor in Africa will be living in urban as opposed to rural areas**

- **In 2003, 58% of SA’s population lived in urban areas**

(UNDP, 2003)

South Africa: Key strategic questions we should be asking….

1. HOW MANY PEOPLE will we need to feed in 2010, 2015, 2020 …… ?
2. WHERE will they be LOCATED?
3. WHERE will the food be SOURCED ?

At the individual level, two options are available for dealing with the food security problem:

- Grow the food
- Buy the food

A G Paterson, 2002

FOOD SECURITY STRATEGY IN S.A. SINCE 1994:

Focus of government, universities, NGO's, overseas developmental agencies:

Food Security for the Rural-Poor

(Premise: The rural-poor can and will grow sufficient food for their own needs and surpluses will be available for sale)


Photo: Alan Manson

Photo: Alan Manson

Drawbacks of current strategy:

- The majority of rural dwellers do not want to farm!
- Vast majority of rural dwellers continue to rely on purchased food.
- More than 60% of SA's population is now urban – growing own food not an option.

The status quo in South Africa

Population

Food security support

RURAL
40%

Government (National, Provincial, ARC)

NGO's, overseas donors

URBAN
60%

?

South Africa's peoples are no longer predominantly rural, and *strategies that focus <u>exclusively</u> on the <u>rural poor</u> are <u>increasingly inappropriate</u>.*

Key issue:

For the vast majority of people in SA, food security implies the availability of ADEQUATE SUPPLIES of quality food *FOR PURCHASING* at an *AFFORDABLE* price.

- Grow it ?
- Buy it ?

South Africa: Key strategic questions we should be asking….

1. HOW MANY PEOPLE will we need to feed in 2010, 2015, 2020 …… ?
2. WHERE will they be located (rural, urban)?
3. WHERE will the food be SOURCED ?

Two options:

- Import
- Grow locally

Dangers linked to imports:

- Dependency on suppliers
- Biofuels threat to world food supplies
- Exchange rate fluctuations
- Local job losses

Grow locally – sensible and safe option

How are we doing in terms of stocking our supermarkets and rural stores with affordable food ?

Food price tsunami of 2007

Food inflation is here to stay

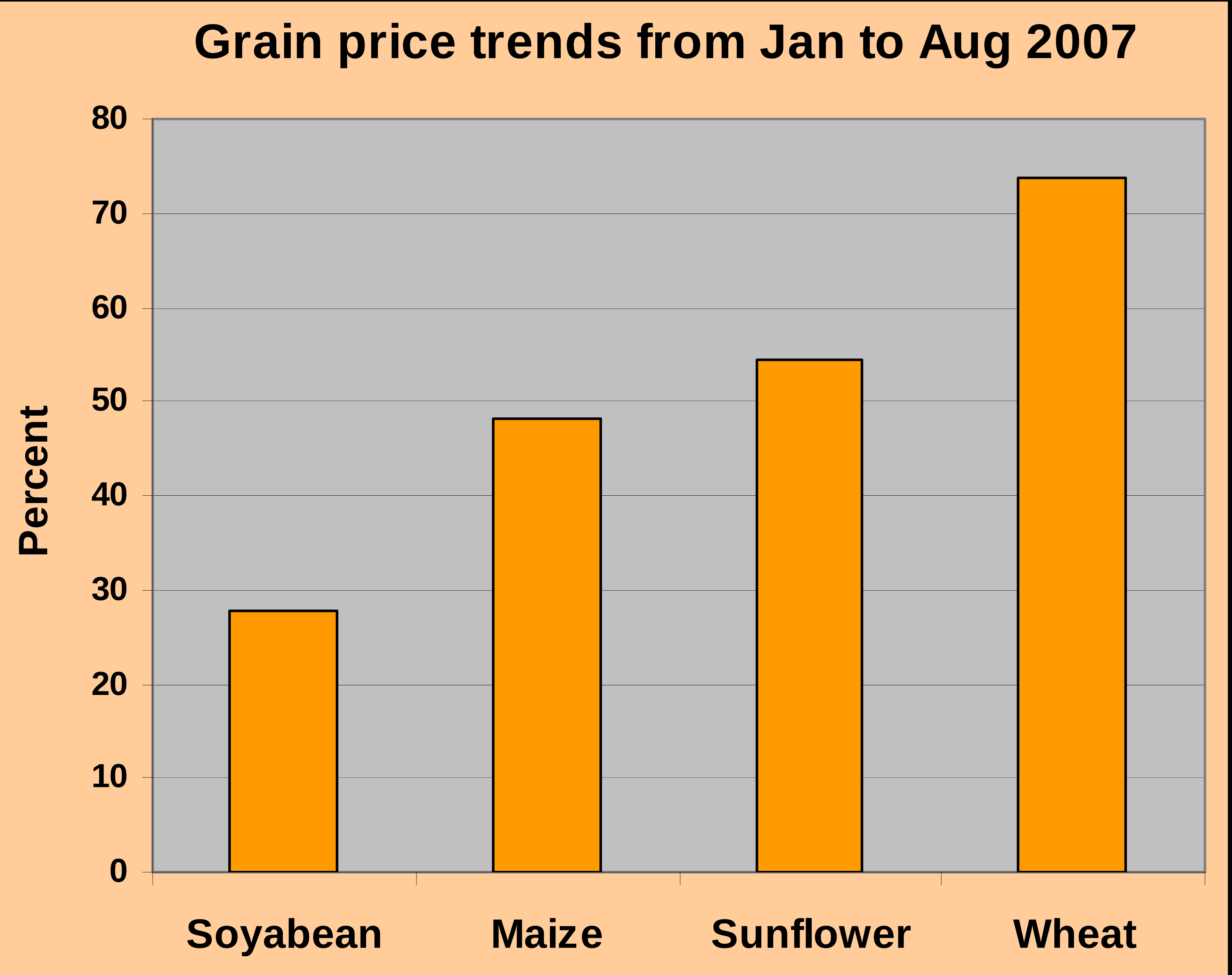
Farmer'sWeekly

Food fright

Finweek

Food inflation likely to remain high through 2008

Old Mutual


Grain price trends from Jan to Aug 2007
Percent
80
70
60
50
40
30
20
10
0
Soyabean
Maize
Sunflower
Wheat

In 2006:

- **Agricultural exports fell marginally**
- **Imports rose by 25%**

Finweek, July 2007

These trends underline need for more comprehensive support of *PRODUCTION AGRICULTURE* (commercial farming)


Photo: Wayne Southwood

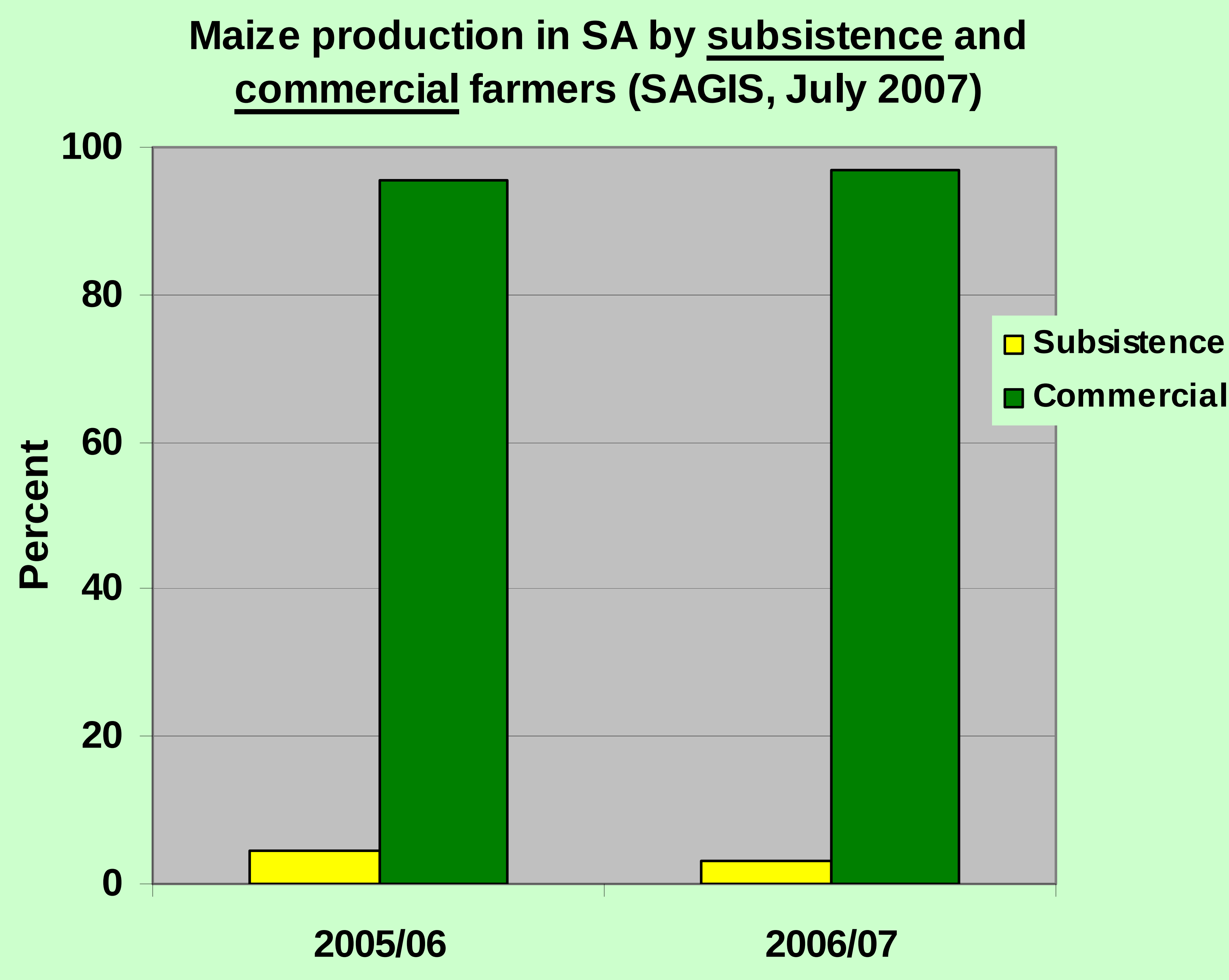

Maize production in SA by subsistence and commercial farmers (SAGIS, July 2007)
100
80
60
40
20
0
Percent
2005/06
2006/07
Subsistence
Commercial

Photo: Alan Manson

PRODUCTION AGRICULTURE

- **Demands extraordinary skills (management, financial, technical, human relations, ….)**
- **Very few (of any colour!) possess such skills**
- **In the national interest to identify them and support them logistically and with top-class extension and research**

South Africa: Key strategic questions we should be asking….

1. HOW MANY PEOPLE will we need to feed in 2010, 2015, 2020 …… ?

2. WHERE will they be located (rural, urban)?

3. WHERE will the food be sourced ?

4. HOW will it be produced ?

Production Agriculture: What System???

- **Organic, biological, biodynamic, permaculture, conventional, ……?**
- **Increasingly heated debate**
- **Intense lobbying of policy-makers, super-market chains and consumers**

ORGANIC	CONVENTIONAL
No chemicals, fertilizers, herbicides, fungicides or pesticides	Chemicals used
Generally lower yields	Potential for higher yields
Price premium	Lower prices

Giving credit where due………

Organic farming:

- highlighting importance of soil organic matter
- dangers of pesticides

Conventional farming:

- providing abundant supplies of affordable food

With >200 million people in sub-Saharan Africa starving, policy-makers need to be aware of the facts.

Prohibition on use of fertilizers

INDEFENSIBLE

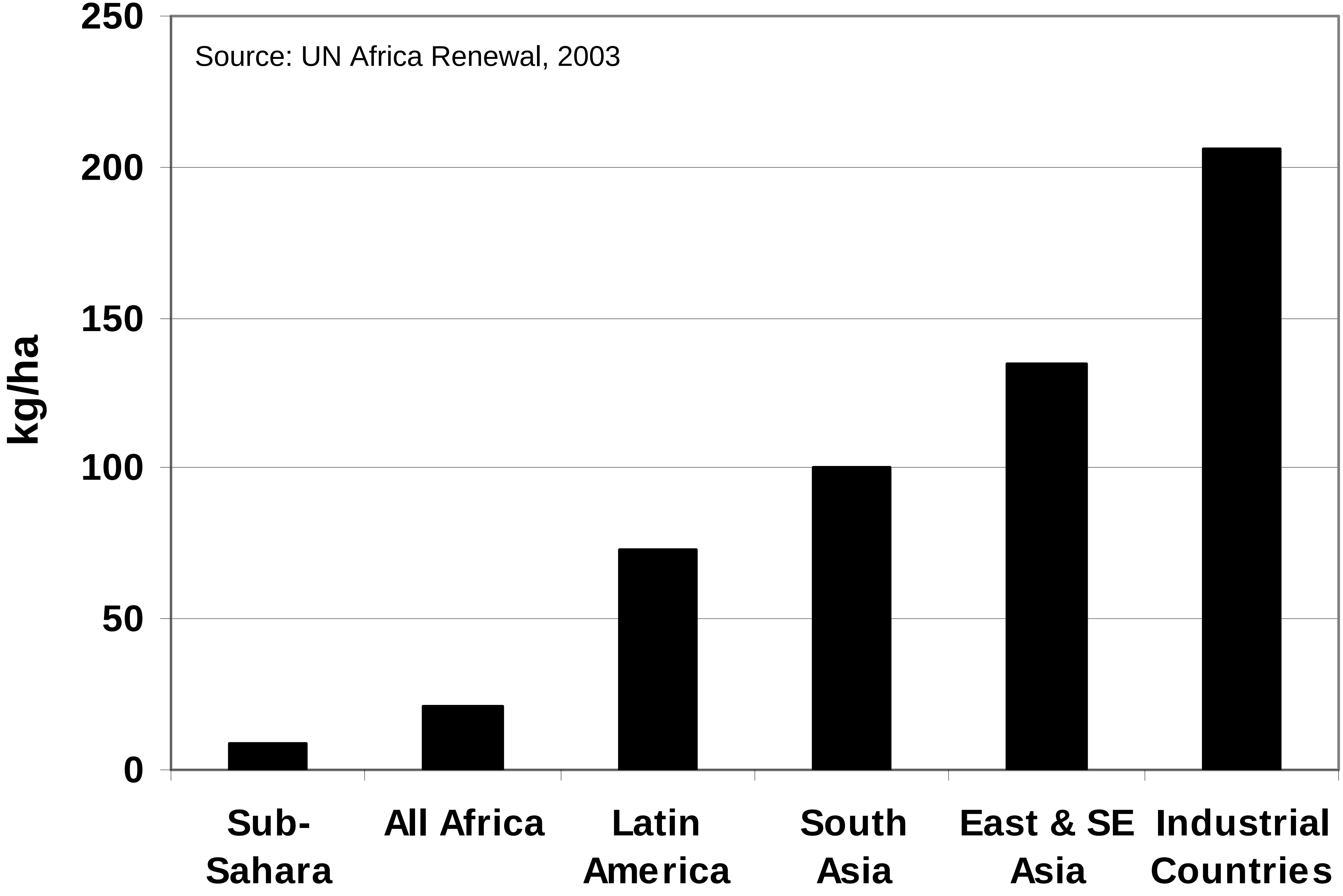
Research shows that, used correctly, fertilizers:

- **Increase organic matter and biological activity in soils**
- **Improve the nutritional value of foods**
- **Ensure optimum yields per unit area; thus restrict land use by agriculture**
- **Pose no hazard to environment**

About 40% of the people alive today owe their life to the production and wide use of fertilizers produced by the Haber-Bosch process

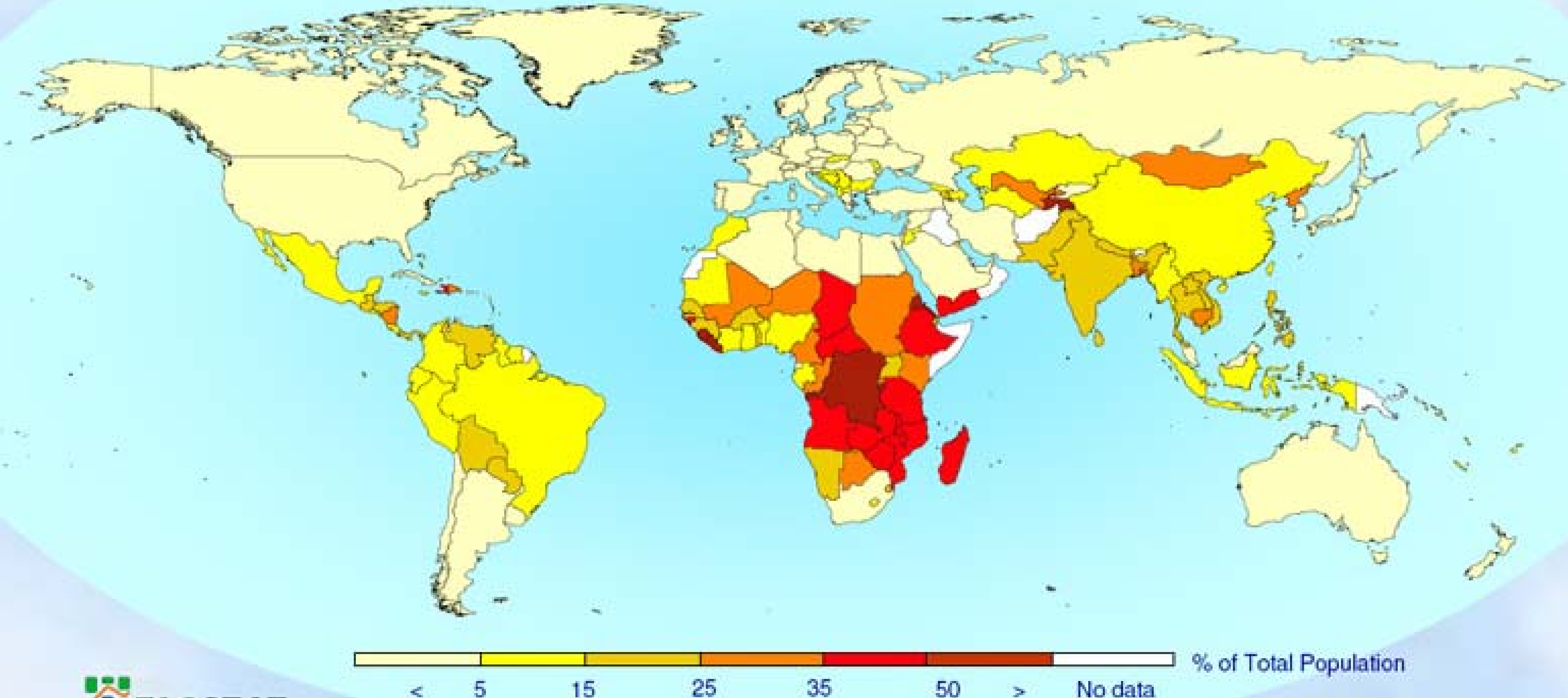
Smil, 2001

Fertilizer Use



Undernourished population

2003



FAOSTAT

Africa is mining its plant nutrients…..

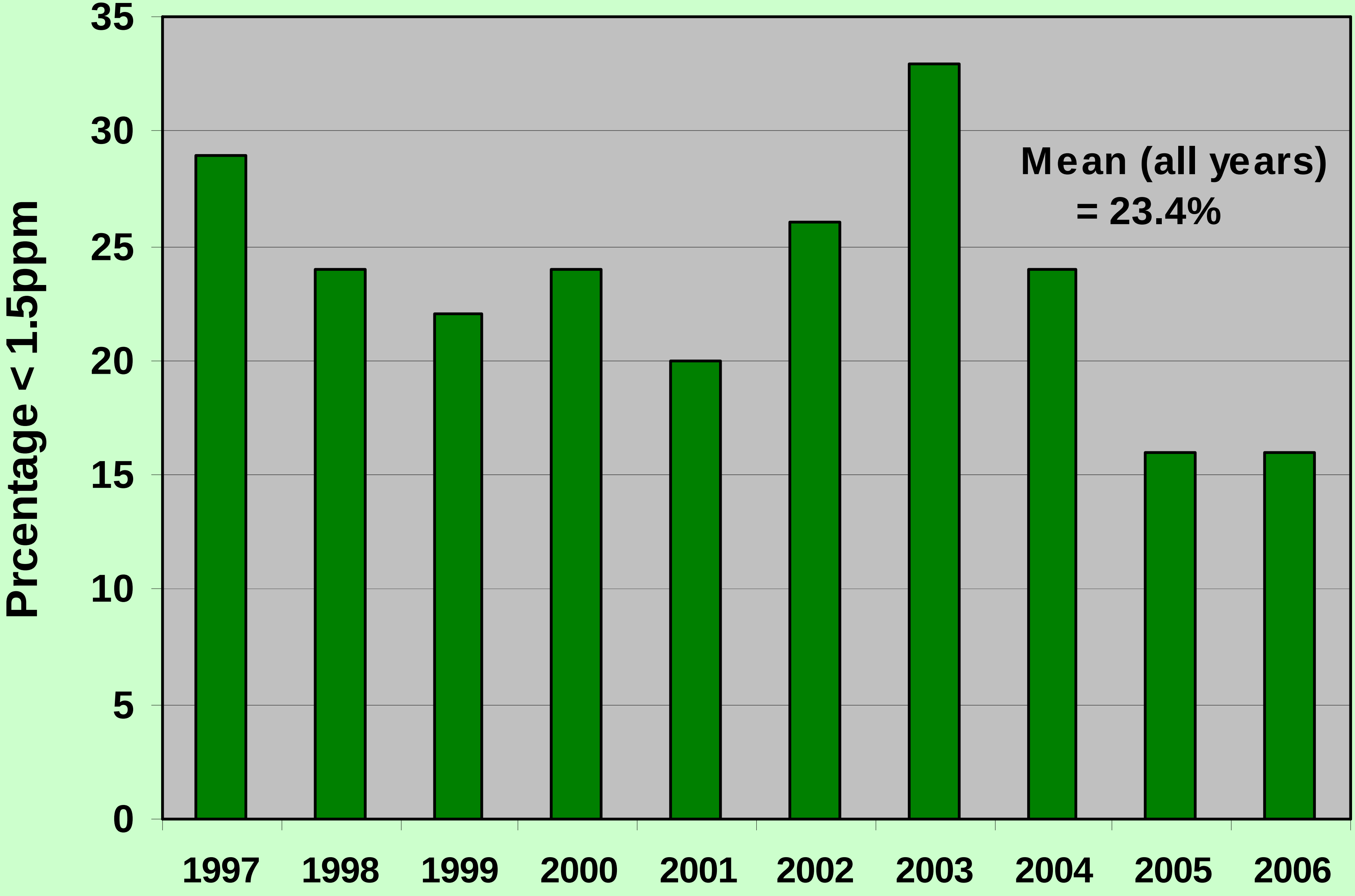
- About 86% of African countries have annual nutrient deficits of > 30 kg NPK/ha per year

- 40% deficits > 60 kg/ha per year

Soil fertility problems in the higher-rainfall eastern half of SA:

- **Severe P, K and Zn deficiencies**
- **Acidity**

Cedara Advisory Services: percentage soil samples deficient in zinc



THE MIDDLE ROAD

(convergence of views)

Forget the battle raging between <u>organic</u> and <u>conventional</u> farming: *<u>new and exciting systems have been developed to produce food sustainably!!!</u>*

'MIDDLE ROAD' SYSTEMS

- **No-Till**
- **Integrated Pest Management (IPM)**
- **Integrated Nutrient Management**

No-Till……

- An agricultural revolution sweeping the world

- Ploughs have become museum pieces

The No-Till system:

- **No-tillage – planting directly into '<u>unprepared</u>' soil**
- **Exploits benefits of a plant-litter soil cover to <u>optimize water use</u>**
- **Involves (minimal) use of <u>'friendly' herbicides and pesticides</u>**
- **Uses <u>fertilizers</u>**
- **<u>Soil health</u> - a primary concern**

Benefits of No-Till:

- **Soil erosion minimized**
- **Water use optimized**
- **Increases in soil organic matter and improved soil health**
- **Drastic reductions in the use of fuel (up to 70%)**
- **High yields**

Earthworm populations

Treatment	Earthworms / m^2
Conventional	0
No-till for 3 yrs	300

Acknowledgement: J Matchett

SUMMARY

- **Sub-Saharan Africa is grossly food insecure, and failing drastic intervention, this situation is likely to deteriorate.**
- **Food security strategies for sub-Saharan Africa must accommodate rapid urbanization.**
- **A new emphasis on *production agriculture* is essential if national food security is to be realized.**

- Increased fertilizer use presents a highly effective and safe means for dramatically increasing food production.

- Increased fertilizer use presents a highly effective and safe means for dramatically increasing food production.
- No-Till farming systems reflect a quantum shift in the context of sustainable food production.

ARC-Institute for Soil, Climate and Water

Zinc in South African Soils: Background and Implications

By Carl Steyn

ARC • LNR

Your Partner in Natural Resource Research and Information

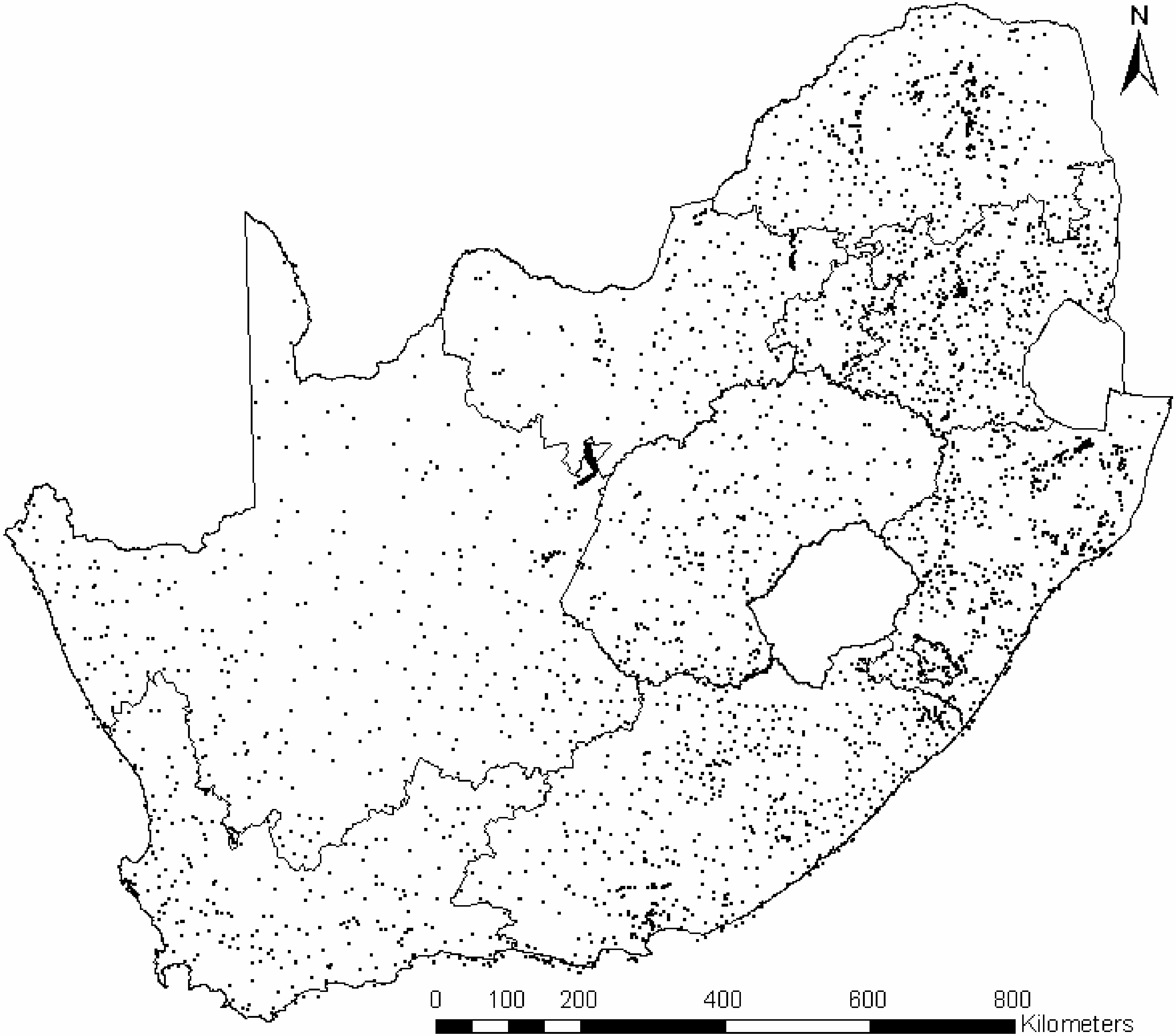

N
0
100
200
400
600
800
Kilometers

Table 2.2. Ranges of concentration (mg kg^{-1}) of trace elements in selected regions and in South Africa

	Concentration ranges					
	USA[1]	Australia and New Zealand [2]	Florida [3]	Belgium [4]	South Africa Total (EPA 3050)	South Africa Available (EDTA)
Cd	0.04-0.8	0.04-2	0-0.33	0.02 –5.3	0.62 - 2.74	0.89 - 1.17
Cr	-	0.5-110	0.89-80.7	1.17 - 119	5.82 - 353	0.87 - 4.52
Ni	4.1-56.8	2-400	1.7-48.5	0.3 - 23	3.43 - 159	0.57 - 9.78
Pb	4-23	<2-200	0.69-42.0	0.0 - 132	2.99 - 65.8	0.93 - 11.9
Zn	**8-126**	**2-180**	**0.89-29.6**	**6.1 - 208**	**12.0 - 115**	**0.62 - 6.03**
Cu	3.8-94.9	1-190	0.22-21.9	1.7 - 39	2.98 - 117	0.84 - 10.6
Co	-	2-170	-	0.03 – 7.7	1.51 - 68.5	0.64 - 16.1

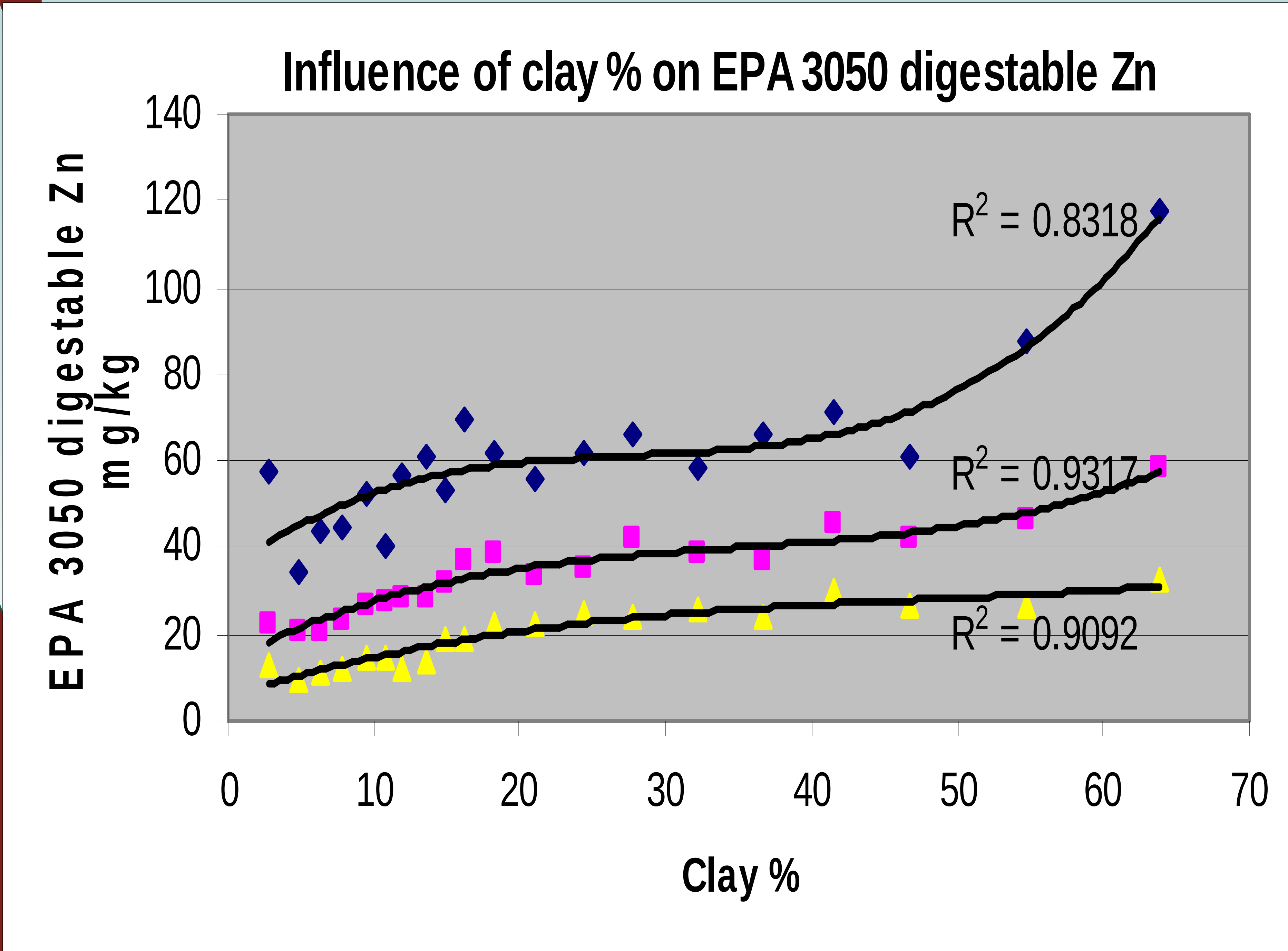
Table 2.4. Derived statistics and recommended limits for total element concentrations (EPA 3050 method).

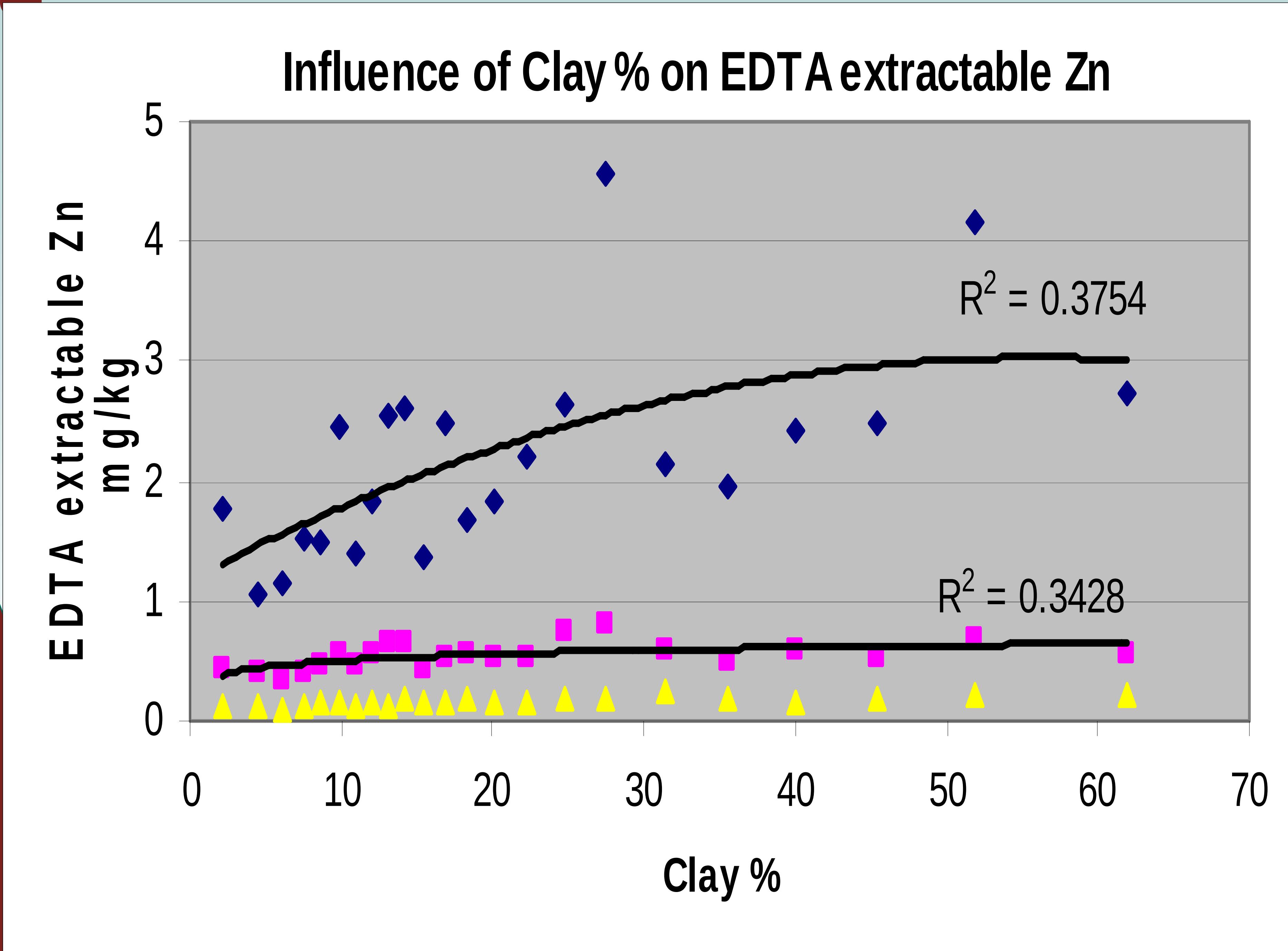
	97.5th %tile concentration (mg kg^{-1})	Samples > Maximum Permissible Limit (%) 1991	1997	Total Investigation level (TIL) (mg kg^{-1})	Total maximum threshold level (TMT) (mg kg^{-1})
Cd	2.7	1	1	2	3
Cr	353	26	26	80	350
Ni	159	62	20	50	150
Pb	66	5	81	56	100
Zn	**115**	**<1**	**32**	**185**	**200**
Cu	117	3	85	100	120
Co	69	18	18	-	-

The 97.5th percentile concentration is the maximum baseline value in Table 2.2.

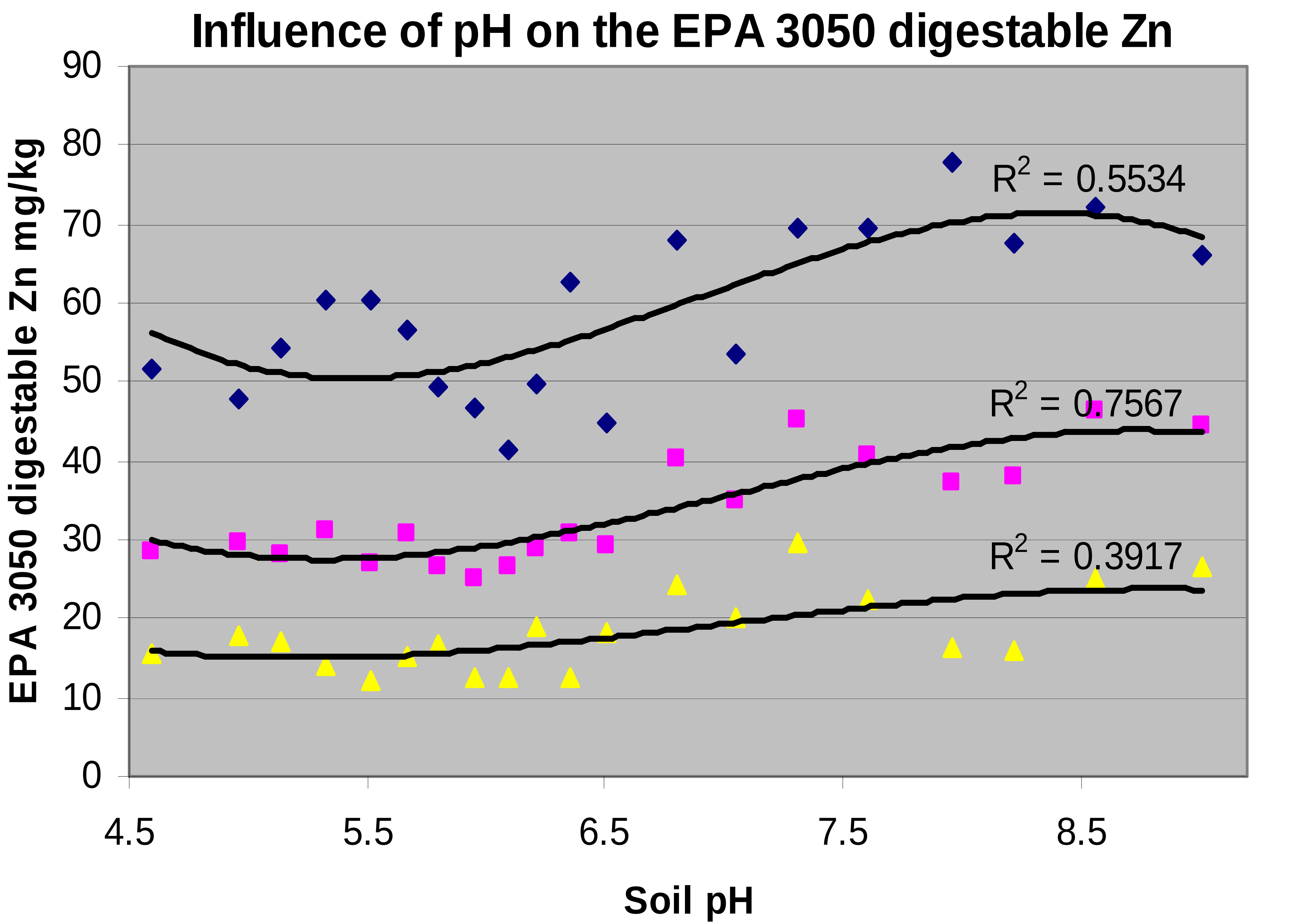
Table 2.5. Derived statistics for trace element deficiencies (NH_4EDTA method)

	Plant deficiency Threshold* (mg kg $^{-1}$)	Samples < deficiency threshold (%)
Zn	**3**	**87**
Zn	**1.5**	**78**
Zn	**0.5**	**40**
Cu	1	29
Co	0.5	21

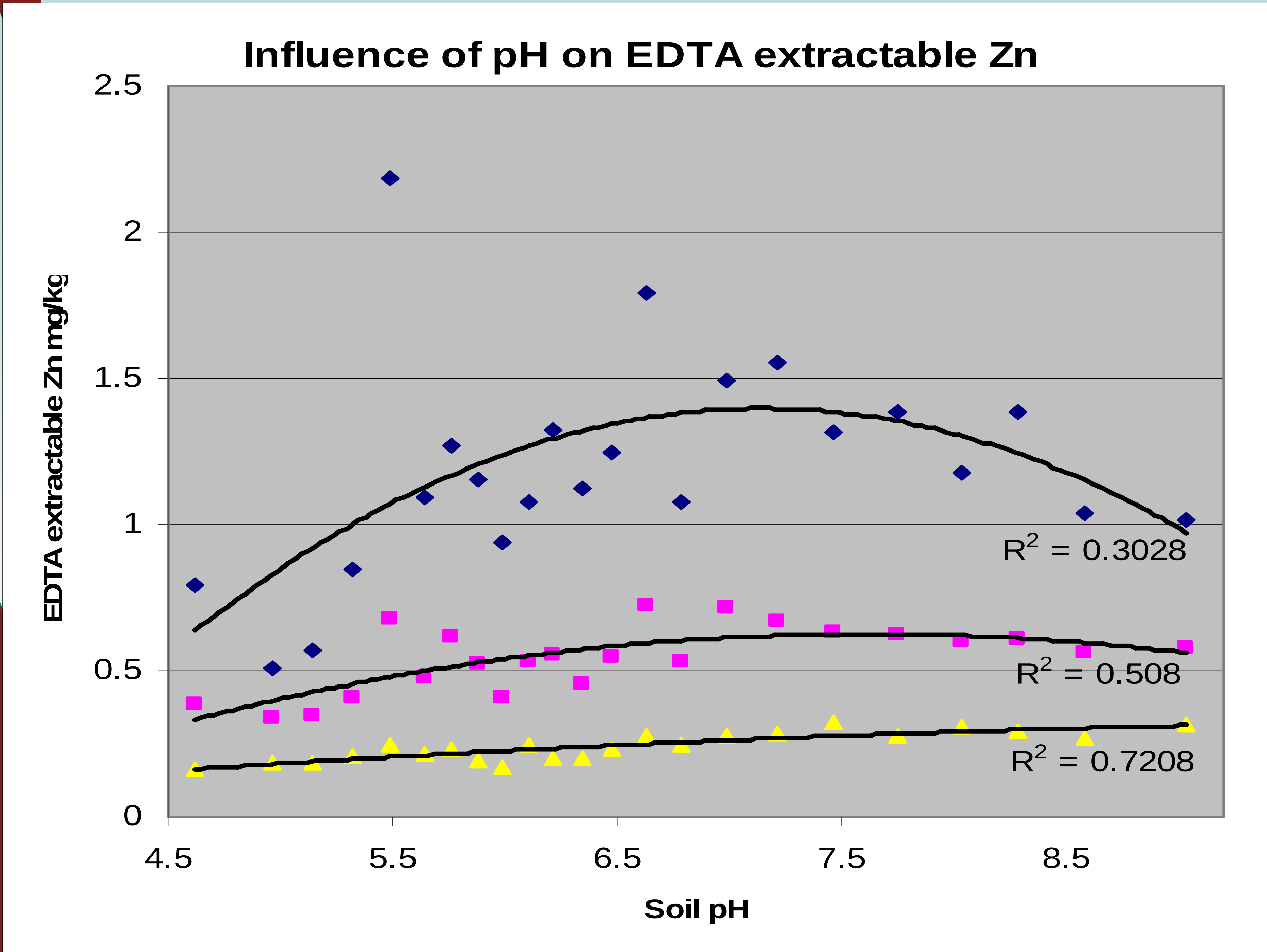

Influence of clay % on EPA 3050 digestable Zn
EPA 3050 digestable Zn mg/kg
Clay %
$R^2 = 0.8318$
$R^2 = 0.9317$
$R^2 = 0.9092$
0
20
40
60
80
100
120
140
0
10
20
30
40
50
60
70



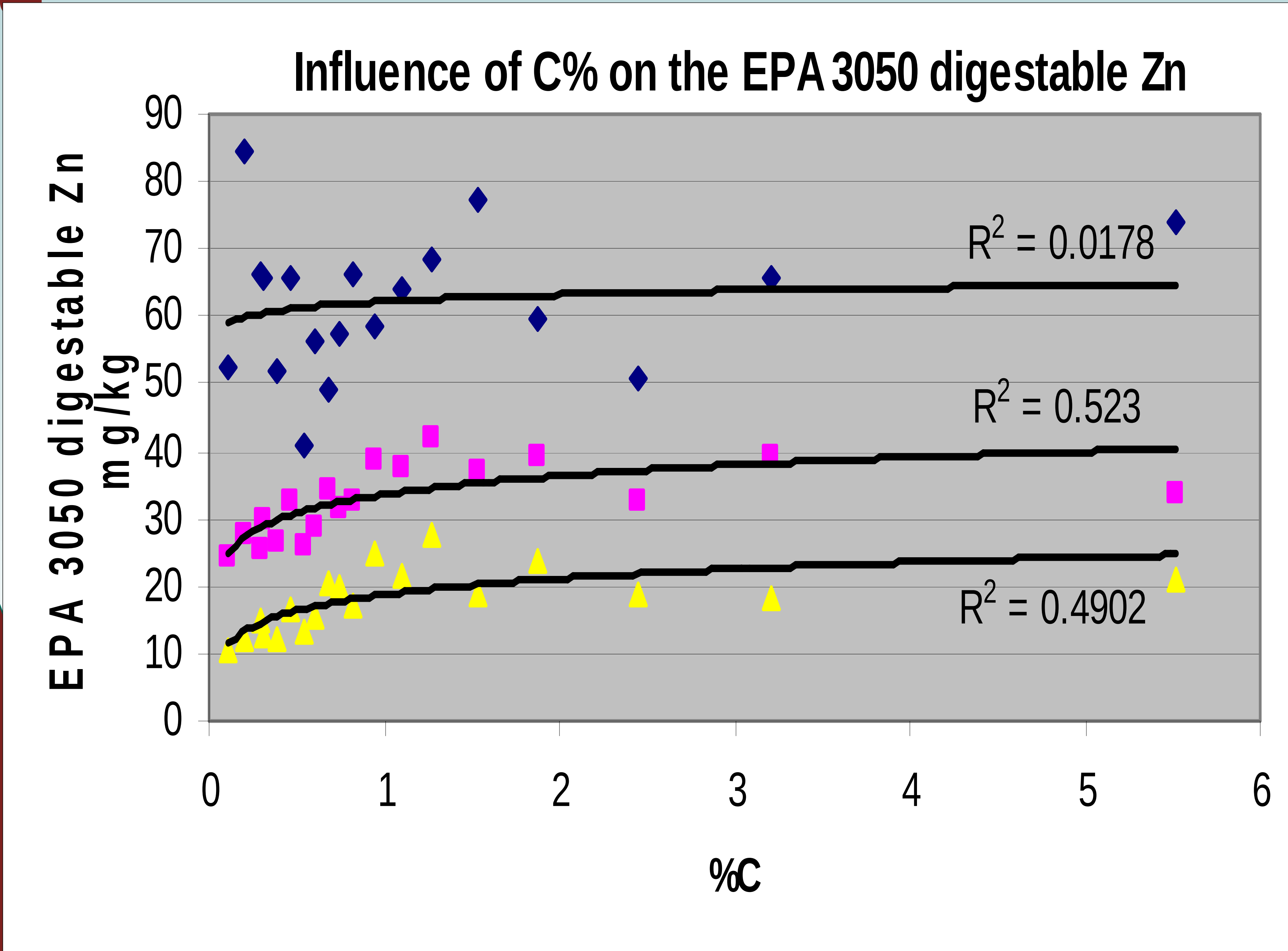
Influence of Clay % on EDTA extractable Zn
EDTA extractable Zn mg/kg
Clay %
R2 = 0.3754
R2 = 0.3428
0
1
2
3
4
5
0
10
20
30
40
50
60
70



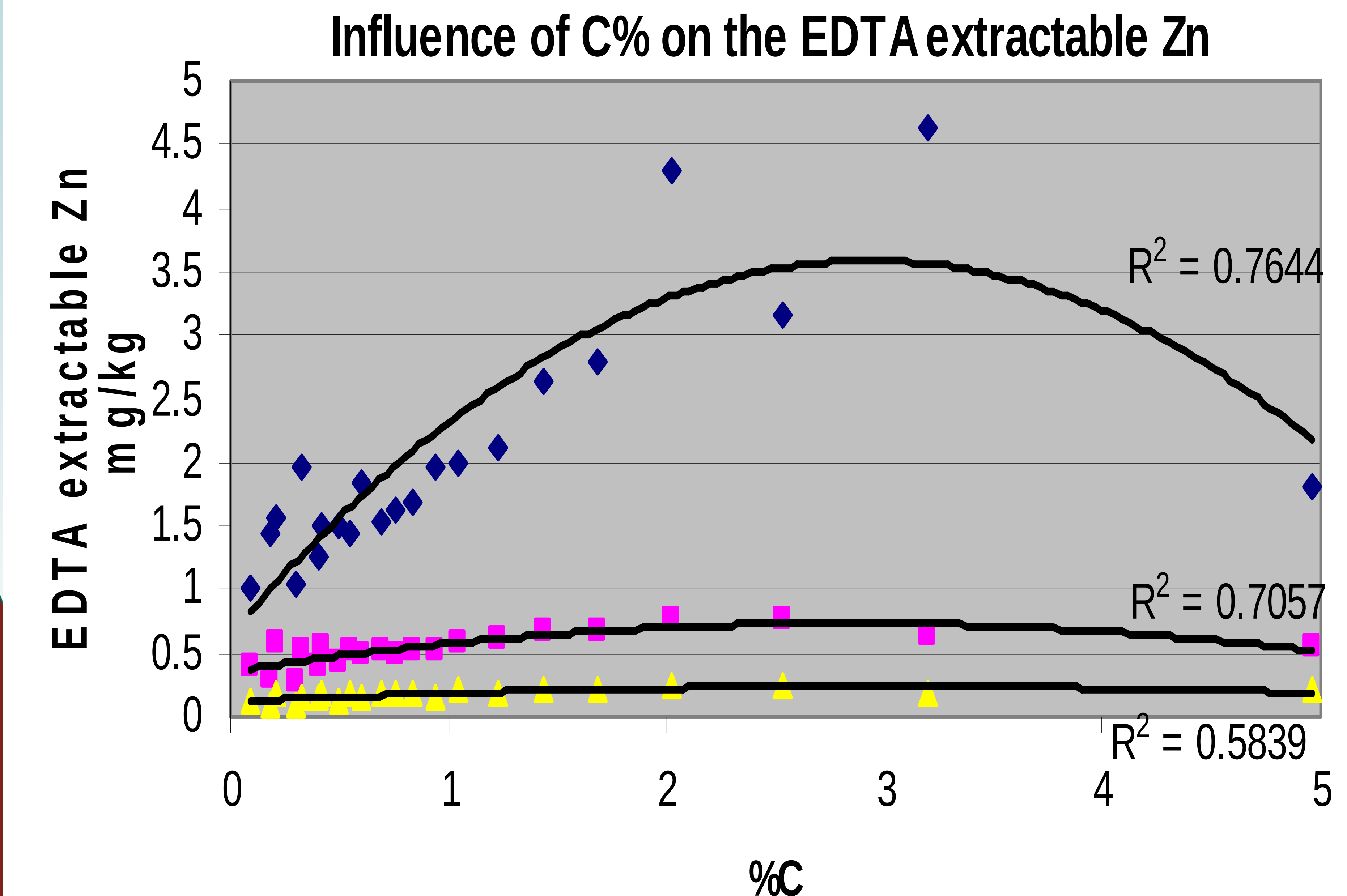
Influence of pH on the EPA 3050 digestable Zn
EPA 3050 digestable Zn mg/kg
Soil pH
0
10
20
30
40
50
60
70
80
90
4.5
5.5
6.5
7.5
8.5
$R^2 = 0.5534$
$R^2 = 0.7567$
$R^2 = 0.3917$



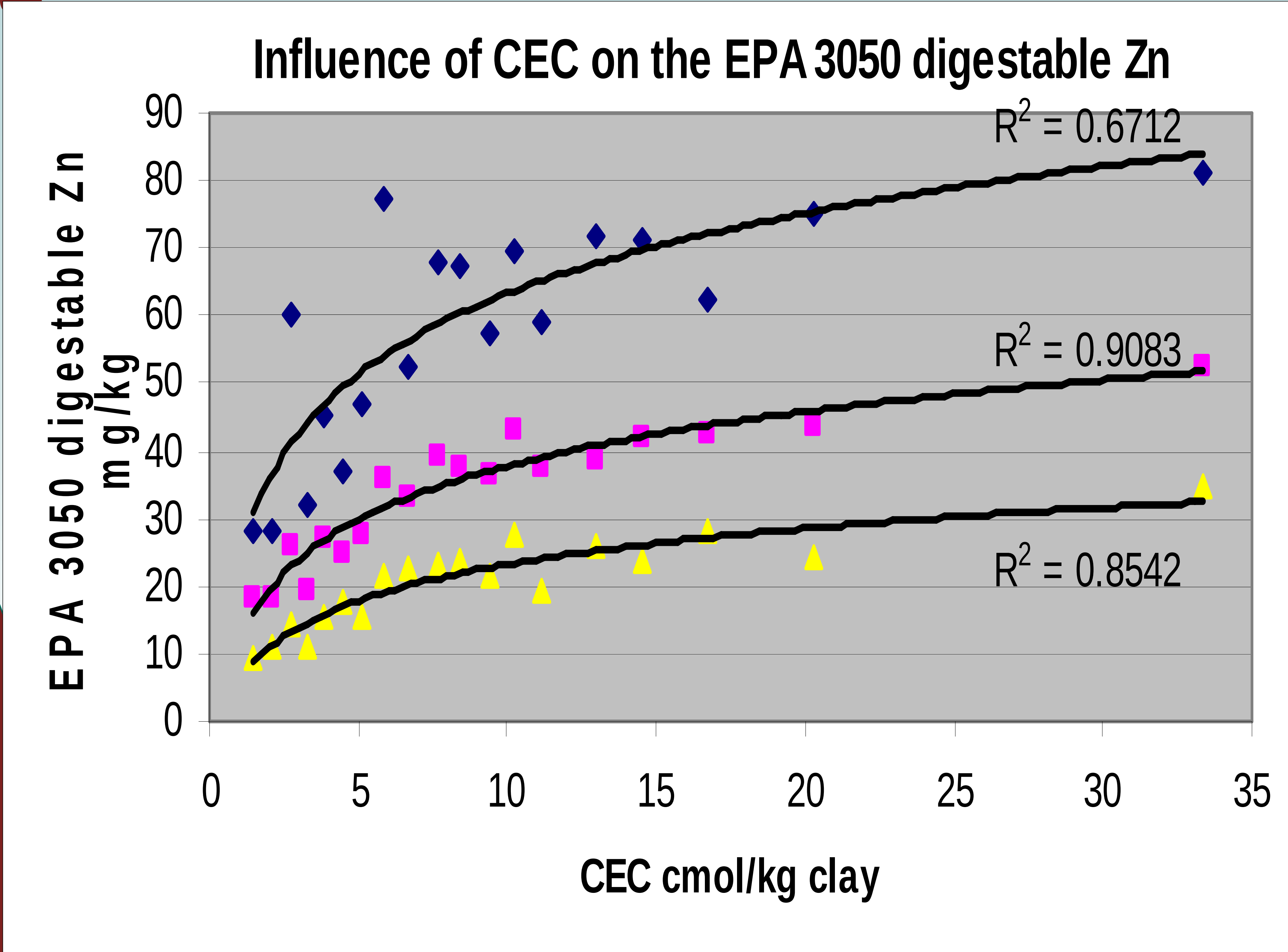
Influence of pH on EDTA extractable Zn
EDTA extractable Zn mg/kg
Soil pH
2.5
2
1.5
1
0.5
0
4.5
5.5
6.5
7.5
8.5
R^2 = 0.3028
R^2 = 0.508
R^2 = 0.7208



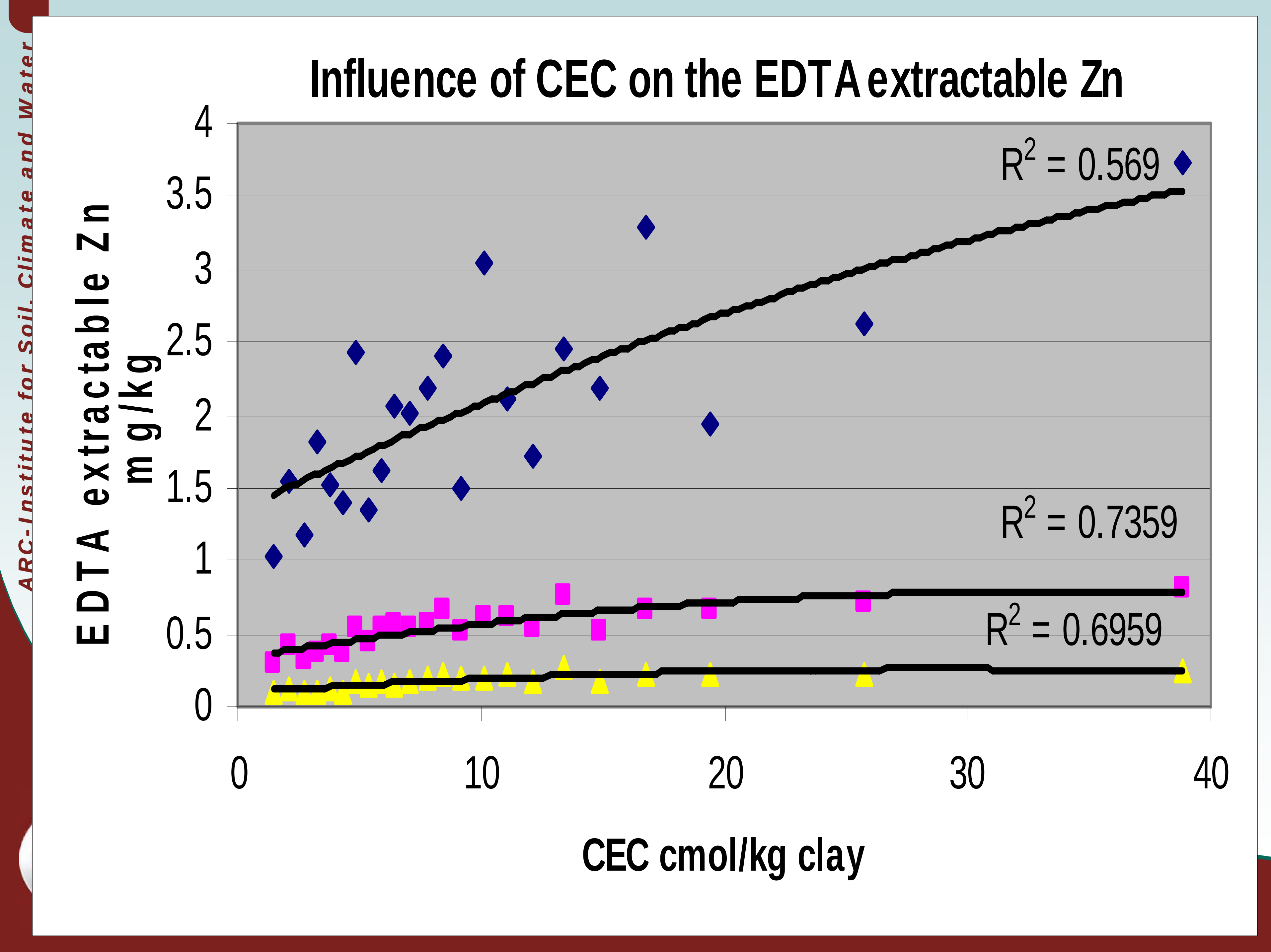
Influence of C% on the EPA 3050 digestable Zn
EPA 3050 digestable Zn mg/kg
90
80
70
60
50
40
30
20
10
0
0
1
2
3
4
5
6
%C
R2 = 0.0178
R2 = 0.523
R2 = 0.4902



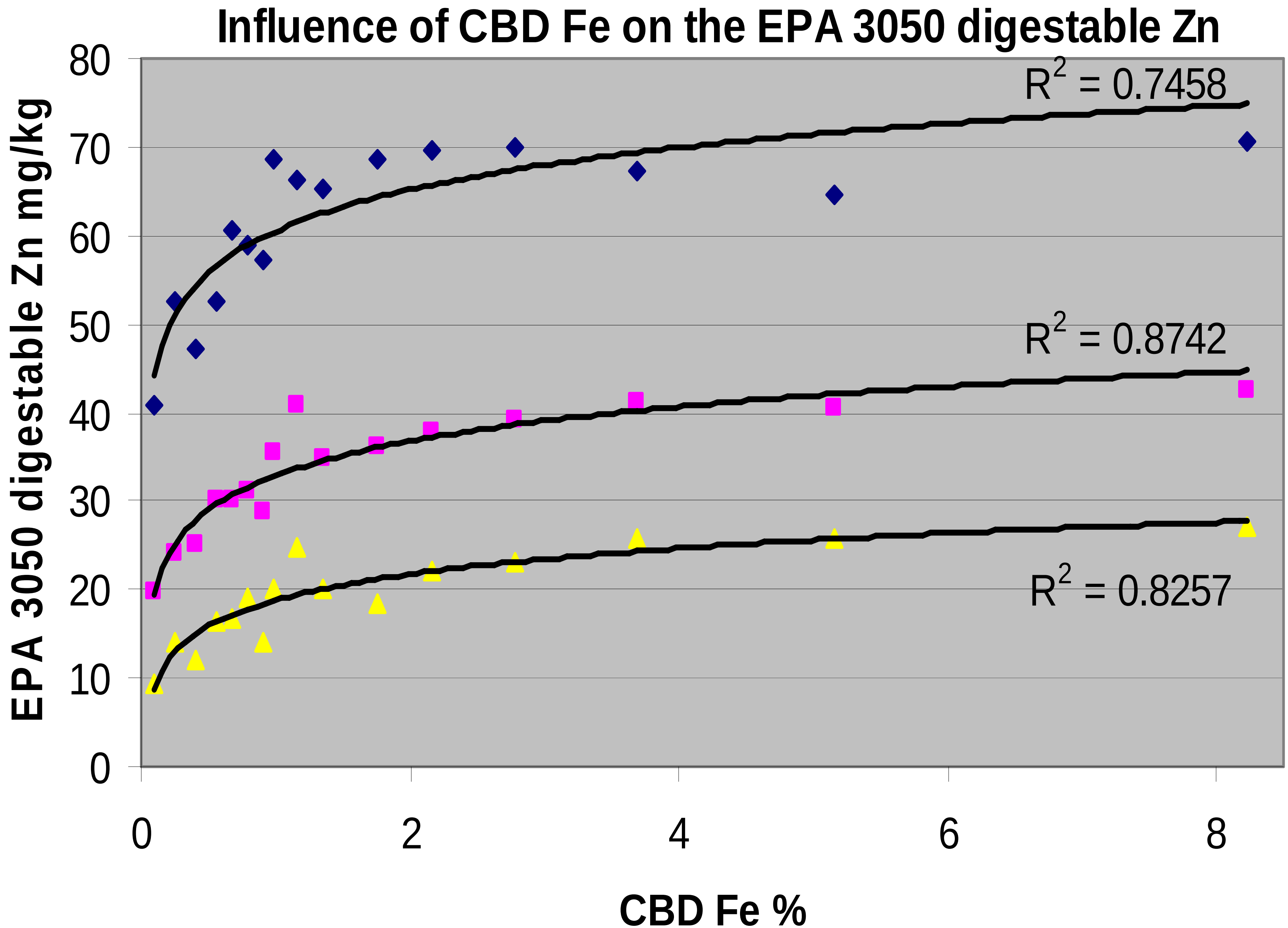
Influence of C% on the EDTA extractable Zn
EDTA extractable Zn mg/kg
%C
R2 = 0.7644
R2 = 0.7057
R2 = 0.5839
0
0.5
1
1.5
2
2.5
3
3.5
4
4.5
5
0
1
2
3
4
5



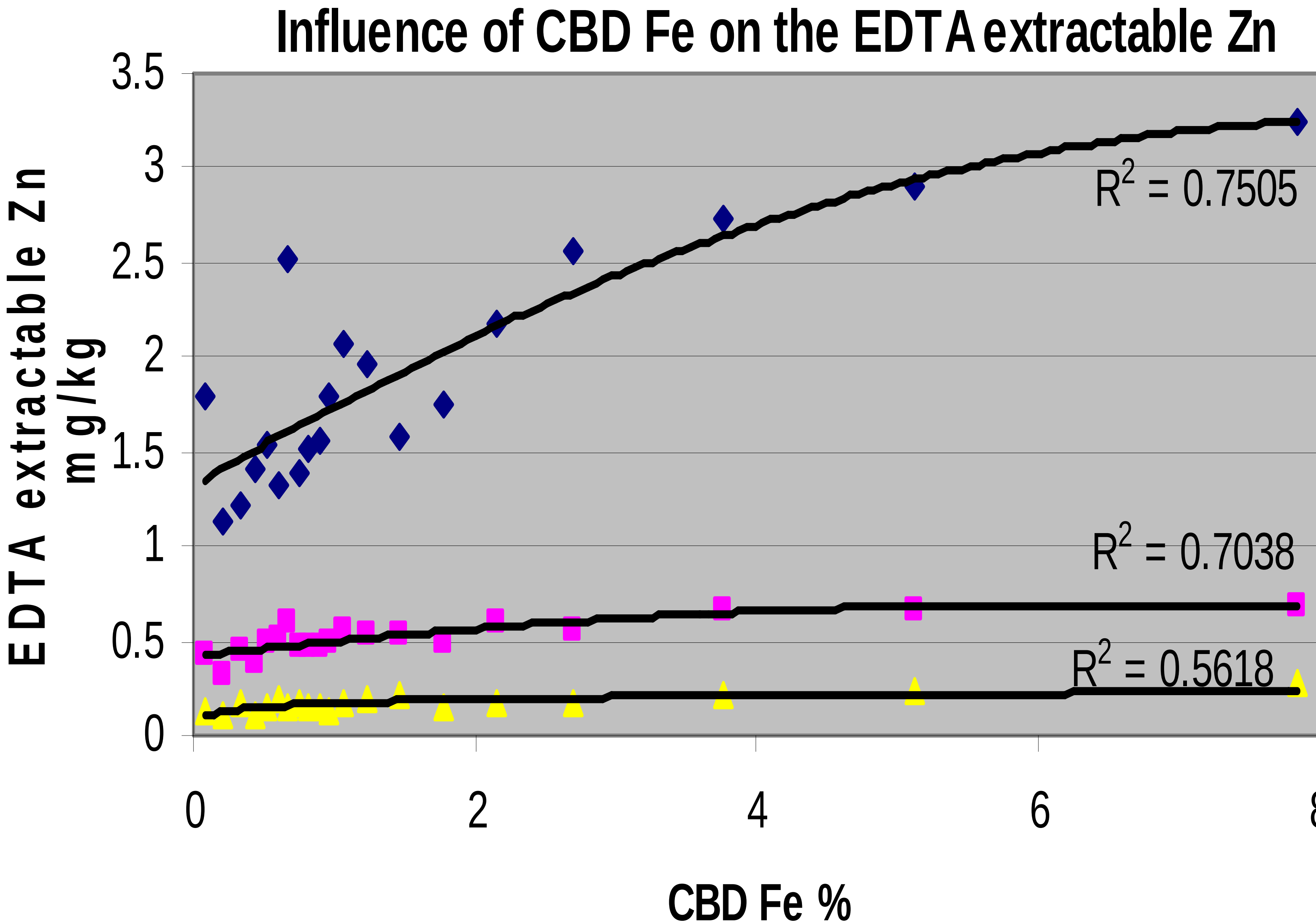
Influence of CEC on the EPA 3050 digestable Zn
EPA 3050 digestable Zn mg/kg
CEC cmol/kg clay
0
10
20
30
40
50
60
70
80
90
0
5
10
15
20
25
30
35
R2 = 0.6712
R2 = 0.9083
R2 = 0.8542



ARC-Institute for Soil, Climate and Water
Influence of CEC on the EDTA extractable Zn
EDTA extractable Zn mg/kg
4
3.5
3
2.5
2
1.5
1
0.5
0
R2 = 0.569
R2 = 0.7359
R2 = 0.6959
0
10
20
30
40
CEC cmol/kg clay



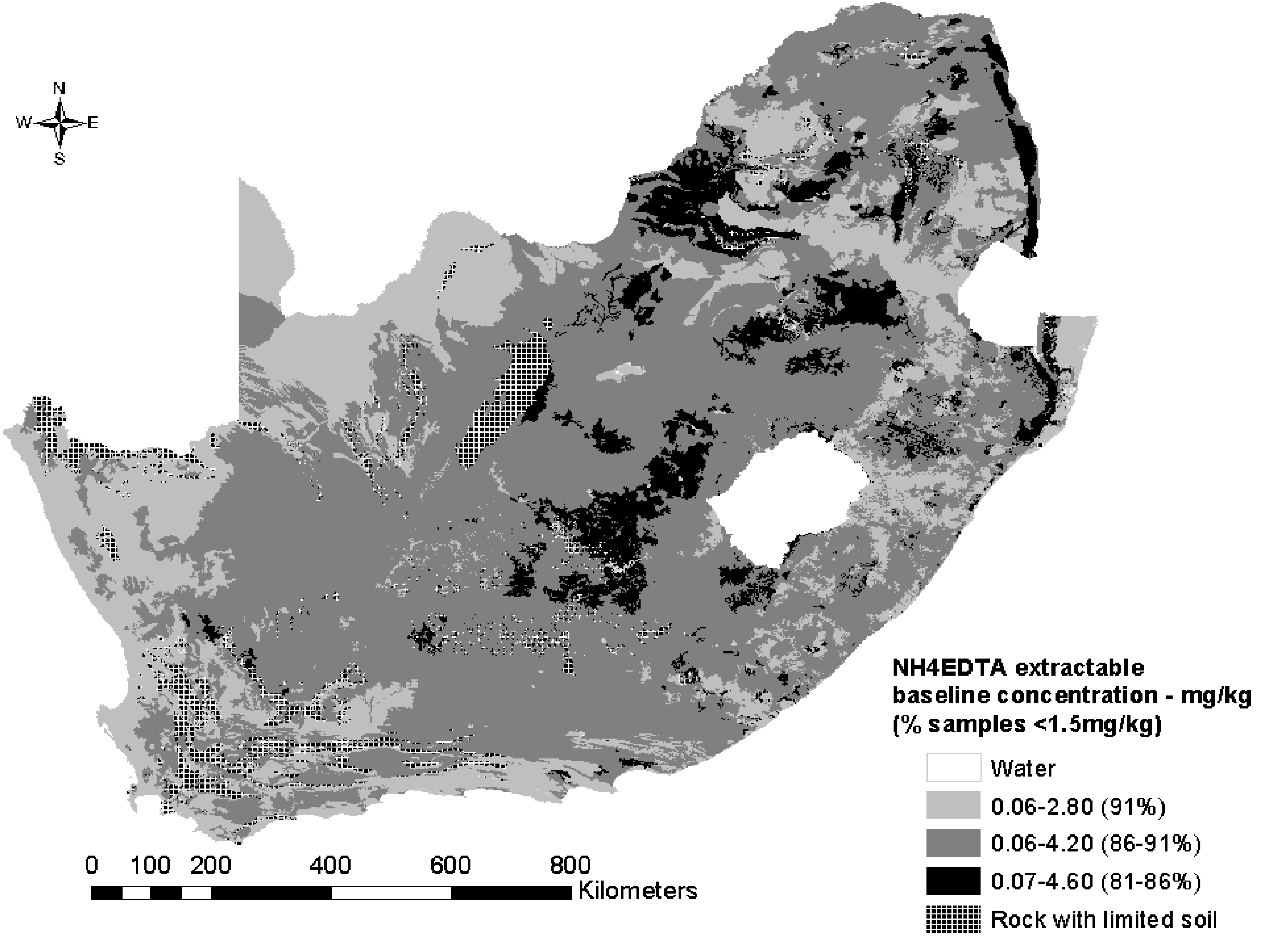
Influence of CBD Fe on the EPA 3050 digestable Zn
EPA 3050 digestable Zn mg/kg
CBD Fe %
$R^2 = 0.7458$
$R^2 = 0.8742$
$R^2 = 0.8257$
0
10
20
30
40
50
60
70
80
0
2
4
6
8


Influence of CBD Fe on the EDTA extractable Zn
EDTA extractable Zn mg/kg
CBD Fe %
3.5
3
2.5
2
1.5
1
0.5
0
0
2
4
6
8
$R^2 = 0.7505$
$R^2 = 0.7038$
$R^2 = 0.5618$

Clay content of South African soil series

- **Clay <6%**
  - All soil series with Clay <6% - class 1
- **Clay 6-15%**
  - Dystrophic – class 1
  - Mesotrophic – class 2
  - Eutrophic – class 3
  - Lime in A-horizon – class 1
- **Clay 15-35%**
  - Dystrophic – class 2
  - Mesotrophic – class 3
  - Eutrophic – class 4
  - Lime in A-horizon – class 2
- **Clay 35-55%**
  - Dystrophic – class 3
  - Mesotrophic – class 4
  - Eutrophic – class 5
  - Lime in A-horizon – class 3
- **Clay >55%**
  - Dystrophic – class 4
  - Mesotrophic – class 5
  - Eutrophic – class 5
  - Lime in A-horizon – class 4

Legend: Class 1 | Class 2 | Class 3 | Class 4 | Class 5


N
W
E
S
NH4EDTA extractable
baseline concentration - mg/kg
(% samples <1.5mg/kg)
Water
0.06-2.80 (91%)
0.06-4.20 (86-91%)
0.07-4.60 (81-86%)
Rock with limited soil
0 100 200 400 600 800
Kilometers

ARC-Institute for Soil, Climate and Water

Table 2. Median concentrations (mg kg^{-1}) of trace elements extracted by EPA method 3050 and hot water for B as related to land use.

ELEMENT	LAND USE[a]			
	Rangeland	Irrigation	Dryland	Resource-poor
B	1.06a	2.45b	1.22c	3.09b
V	89.8a	107.3a	102.0a	68.7a
Cr	136a	214b	127a	114a
Mn	538a	719ab	744b	311c
Fe	30934a	44536a	38041a	33697a
Co	19.8a	25.4a	20.9a	12.2b
Ni	61.8a	77.3a	62.1a	35.3b
Cu	40.3a	56.3b	44.3ab	25.4c
Zn	**45.1a**	**76.2b**	**55.6c**	**43.1a**
As	1.45a	4.62b	0.85c	1.84a
Se	1.854a	0.242bc	0.578b	0.230c
Mo	0.448a	0.251b	0.600c	0.149d
Cd	0.234a	0.173b	0.485c	0.213ab
Pb	10.8a	17.8b	22.2b	21.9b

Table 1. Median concentrations (mg kg^{-1}) of trace elements extracted by NH_4EDTA as related to land use.

ELEMENT	LAND USE[a]			
	Rangeland	Irrigation	Dryland	Resource-poor
V	1.58a	1.96a	1.86a	0.43b
Cr	0.266a	0.187a	0.214a	0.215a
Mn	234a	381b	286ab	102c
Fe	448a	196b	211b	103c
Co	6.07ab	10.29c	7.39ac	1.78d
Ni	5.87a	8.65a	5.24a	1.85b
Cu	5.22a	10.87b	5.51a	3.13c
Zn	**1.98a**	**11.32b**	**4.12c**	**3.65c**
As	0.210a	0.196a	0.198a	0.217a
Se	0.481a	0.358a	0.490a	0.616a
Mo	0.148a	0.132a	0.137a	0.111a
Cd	0.203a	0.132bc	0.159b	0.123c
Pb	3.38a	4.51b	5.03b	6.03b

ARC-Institute for Soil, Climate and Water

Table 6. The percentage of samples lower than suggested deficiency thresholds for trace elements extracted by EPA method 3050 and hot water soluble B as related to land use.

Element and threshold	Percentage of samples lower than thresholds for the different land uses			
	Rangeland	Irrigation	Dryland	Resource-poor
B<1[a]	65.6[e]	8.3	45.9	5.6
Co<5[b]	18.9	16.7	12.6	19.4
Cu<5[b]	5.8	0.0	0.0	2.8
I<1[c]	17.7	12.5	3.6	2.8
Mo<0.1[d]	17.2	70.8	12.6	88.9
Se<0.6[f]	52.1	87.5	50.5	91.7
Zn<20[b]	**7.6**	**0.0**	**0.9**	**0.0**

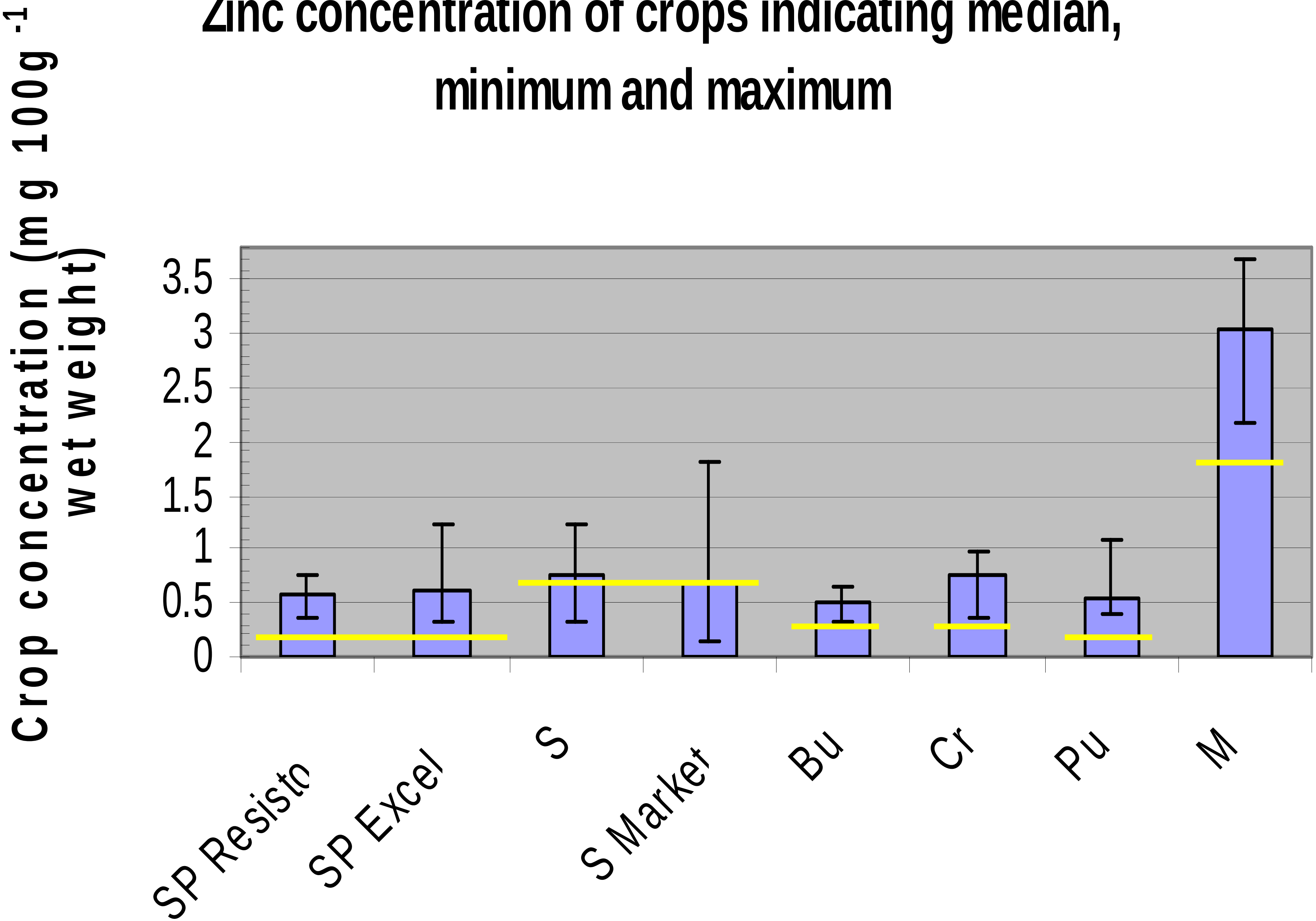
ARC • LNR

Table 7. The percentage of samples lower than suggested deficiency thresholds for trace elements extracted by NH_4EDTA as related to land use.

Element and threshold	Percentage of samples lower than thresholds for the different land uses			
	Rangeland	Irrigation	Dryland	Resource-poor
Co<0.5[a,b]	11.7[d]	0.0	5.4	55.6
Cr<0.05[b]	16.9	37.5	33.3	11.1
Cu<1[a,e]	7.0	4.2	0.9	0.0
Fe<35[a]	4.2	4.2	4.5	5.6
I<0.05[c]	20.7	20.8	31.5	0.0
Mn<5[a]	0.0	0.0	0.0	0.0
Mo<0.05[a]	62.4	75.0	76.6	100.0
Se<0.05[a,c]	39.9	12.5	19.8	0.0
Zn<1.5	**52.1**	**0**	**7.2**	**13.9**
Zn<3[a]	**85.0**	**8.3**	**37.8**	**69.4**

- After the discovery that vitamin A deficiencies could be lethal micronutrients has received more attention.
- Humans require at least 50 known nutrients, in adequate amounts consistently, to live healthy and productive lives.
- Global food systems are failing to provide adequate quantities of all the essential nutrients to people in the developing world.

Zinc concentration of crops indicating median, minimum and maximum



Multiple regression between plant Zn (dry mass) and soil properties

Crop	***Soil analysis***	***R^2***
Sweet Potato cv Resisto	pH H_2O, Clay, NH_4EDTA Zn	0.79
Sweet Potato cv Excel	NH_4NO_3 Zn	0.91
Spinach	pH H_2O, CEC, NH_4EDTA Zn	0.78
Carrots	NH_4NO_3 Zn	0.82
Butternut	pH H_2O, CEC, NH_4NO_3 Zn	0.81
Pumpkin leaves	pH H_2O, CEC, NH_4NO_3 Zn	0.39
Maize	NH_4NO_3 Zn	0.82

carl@arc.agric.za

CURRICULUM VITAE: THABANG PAMELA MATLHAFUNA

EMPLOYMENT HISTORY

August 2005 to date-
Programme Officer and Communication Officer, The Micronutrient Initiative (MI), Africa Regional Office

MI is a not for profit organization specializing in addressing vitamin and mineral deficiencies. MI supports and promotes food fortification and supplementation programmes in Africa, Asia and Latin America and provides technical and operational support in those countries where vitamin deficiency is most prevalent. Recognizing the critical role of nutrition in meeting the Millennium Development Goals (MDG), MI Africa promotes an integrated approach to addressing those deficiencies that are known to contribute most to the burden of disease and death among the vulnerable populations and have the greatest impact on mental impairment and productivity. These include deficiencies in Vitamin A, Iodine, Iron, Zinc and Folic Acid.

As a Programme Officer I provide direct support to regional director where needed to improve programme delivery including country visits, liaison with country coordinators and attendance at international and regional meetings. Among my other duties include:

- The focal point for both HIV and Communication programmes in MI Africa. For HIV programmes it entails reviewing and being up to date with current literature in HIV and Nutrition and make recommendations on how they affect MI programmes
- Advocacy role at international and country level for inclusion of micronutrient programmes particularly vitamin A and zinc into national health programmes.

Senior Dietician, Mafikeng/ Bophelong Hospital Complex ARV Unit December 2004 to July 2005

DUTIES

- Management of the Nutrition Unit in the institution, complying with the required reporting schedules- Statistical reporting, compilation of comprehensive synopsis, supervision of community and student dieticians on clinical placement.
- To initiate and assist in training of health professionals with respect to nutrition and diet therapy with focus on nutrition screening, monitoring and evaluation of nutrition care process of clients
- Advocacy for nutrition programmes in the institution, assist with the development of policies for the ARV and Dietetics units
- Liaise with other institutions and health care members for the treatment and management of HIV and AIDS patients to develop nutrition guidelines and education material for ARV unit

Community Service Dietitian, Mafikeng Provincial Hospital, Mafikeng North West Province 2003

DUTIES

- Establishing a nutrition unit at the institution
- Provision of nutrition/ dietetic services to patients; ensure follow up for those clients who need continued nutrition monitoring

EDUCATION HISTORY and TRAINING

1998-2002- Bsc (Dietetics), Medical University of Southern Africa (MEDUNSA), Garankuwa Pretoria

PROVIDING ZINC TO POPULATIONS THROUGH SUPPLEMENTATION, FORTIFICATION AND FOOD BASED APPROACHES

Thabang Matlhafuna, The Micronutrient Initiative

SUMMARY

According to available data on stunting prevalence rates and the percent of individuals thought to be at risk of zinc deficiency in Sub Saharan Africa is estimated to be 25% compared to an estimated 10% in North Africa.[1] Data from Food and Agricultural Organisation (FAO) food balance sheets suggest one third of the world's population to reside in countries identified as at high risk of zinc deficiency and one and a half in countries with moderate risk for deficiency. Sub optimal zinc levels are due to inadequate dietary zinc intakes possibly caused by consumption of foods with low zinc content or intake of foods with low bioavailable zinc. Impaired absorption and utilisation of zinc has also been associated with physiological and pathological conditions.

In order to tackle this problem a few strategies have been put forward to address zinc deficiency, mainly supplementation, food fortification and dietary diversification strategies.
Supplementation intervention trials have been conducted in various parts of the world to assess the benefit and impact of the strategy. The study results indicate that zinc has a critical role in child development through eliciting a positive impact on child growth, a reduction in morbidity and also showing a reduction in adverse outcomes in pregnancy.[2]

Fortification of cereals with zinc is considered to be one of the promising strategies to alleviating zinc deficiency in zinc deficient countries. Mass fortification programmes are structured so as their implementation and success does not require changes in the eating/ dietary habits of the populations and they are a long term strategy that may effectively prevent the development of vitamin and mineral deficiencies in populations.[3]

Dietary diversification strategies aim to increase the total dietary zinc content and absorption from household diets by changing food selection patterns and maintaining some of the traditional food preparation methods which make a positive contribution to increasing the bioavailability of zinc in foods. Four main dietary strategies are available for use at household level to enhance the content and bioavailability of zinc and other vitamin and minerals.[4]

1. Breastfeeding and complementary feeding practices
2. Increasing the production and consumption of foods high in zinc
3. Food processing to reduce dietary phytate[5] content
4. Increasing the intake of foods known to enhance absorption of zinc

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[1] Hotz C, Brown KH, guest editors. International Zinc Nutrition Consultative Group (IZINC) Technical Document 1: Assessment of the risk of zinc deficiency in populations and options for its control. Food and Nutrition Bulletin 2004; 25:S130-S140
[2] Hotz C, Brown KH, guest editors. International Zinc Nutrition Consultative Group (IZINC) Technical Document 1: Assessment of the risk of zinc deficiency in populations and options for its control. Food and Nutrition Bulletin 2004; 25:S96-S105
[3] IZINC Technical Brief No. 4: Zinc Fortification 2007
[4] IZINC Technical Brief No. 5: Preventing zinc deficiency through diet diversification and modification
[5] Pytate: myo-inositol hexaphosphate and other inositol phosphates, a known inhibitor of iron and zinc absorption

Micronutrient Initiative

Solutions for hidden hunger

Providing Zinc to Populations through Supplementation, Fortification and Food Based Approaches

Thabang Matlhafuna

16 August 2007

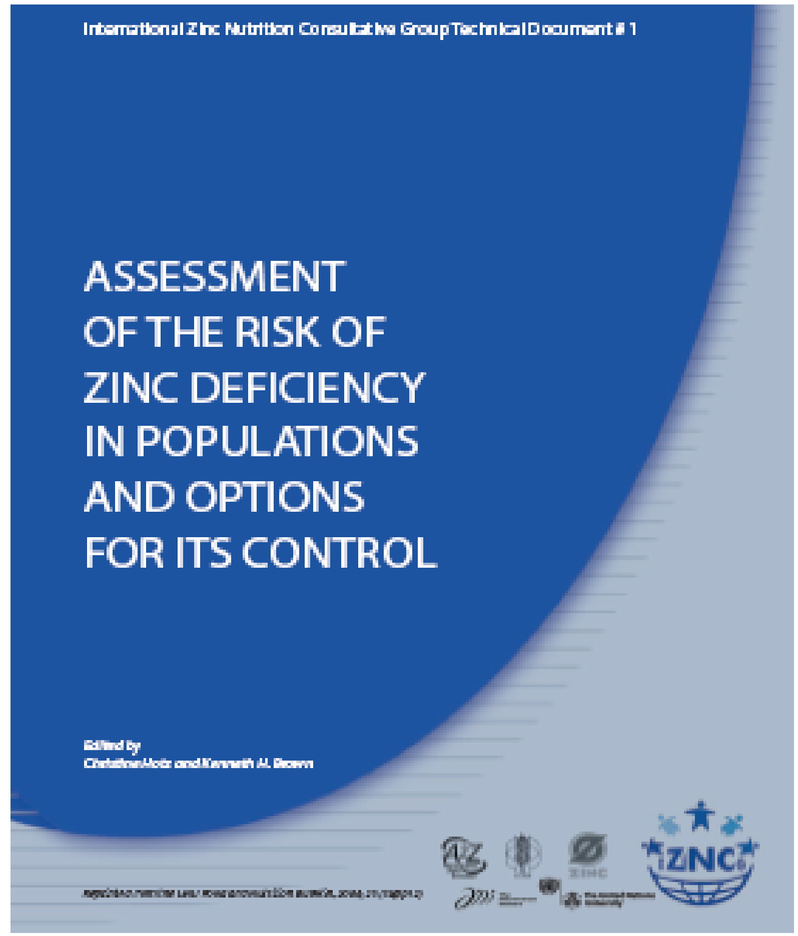
www.micronutrient.org

About the MI

- MI was established in 1992 as an international agency that addresses the problem of micronutrient malnutrition (deficiencies of vitamins and minerals) in developing countries and has had strong ongoing support from CIDA.
- MI's mission is to stimulate and support national actions to eliminate micronutrient malnutrition, assuring universal coverage and sustained impact on the health and well-being of people.
- MI supports and promotes an integrated approach to address micronutrient deficiencies that includes dietary improvement, food fortification and supplementation programs.
- MI is governed by an international Board of Directors, with senior representation from the World Bank, UNICEF, the World Food Programme and the Canadian International Development Agency (CIDA).
- We have offices in Ottawa (Canada), Johannesburg (South Africa), New Delhi (India) as well as country offices/coordinators in Nepal, Pakistan and Bangladesh, Indonesia, Ethiopia, Kenya, Nigeria and Senegal.

MI Zinc- Highlights for 2006-07

- **MI continues to support IZiNCG:**
  - Technical assistance to countries (study protocol, proposals, national surveys, etc.)
  - Development of operational research proposals for various countries including Senegal and Malawi
  - Web-based information sharing service
  - Production of technical and advocacy brochures to promote investment in zinc and accelerate implementation of supplementation
  - State of the art papers on zinc intervention strategies to be published in Food & Nutr Bull in 2008
- **MI participated in the Zinc Task Force regional meetings on therapeutic zinc**



Outline

- Importance of zinc in nutrition/health
- Consequences of zinc deficiency
- Estimated risk of zinc deficiency globally and in Africa
- Strategies to address zinc deficiency

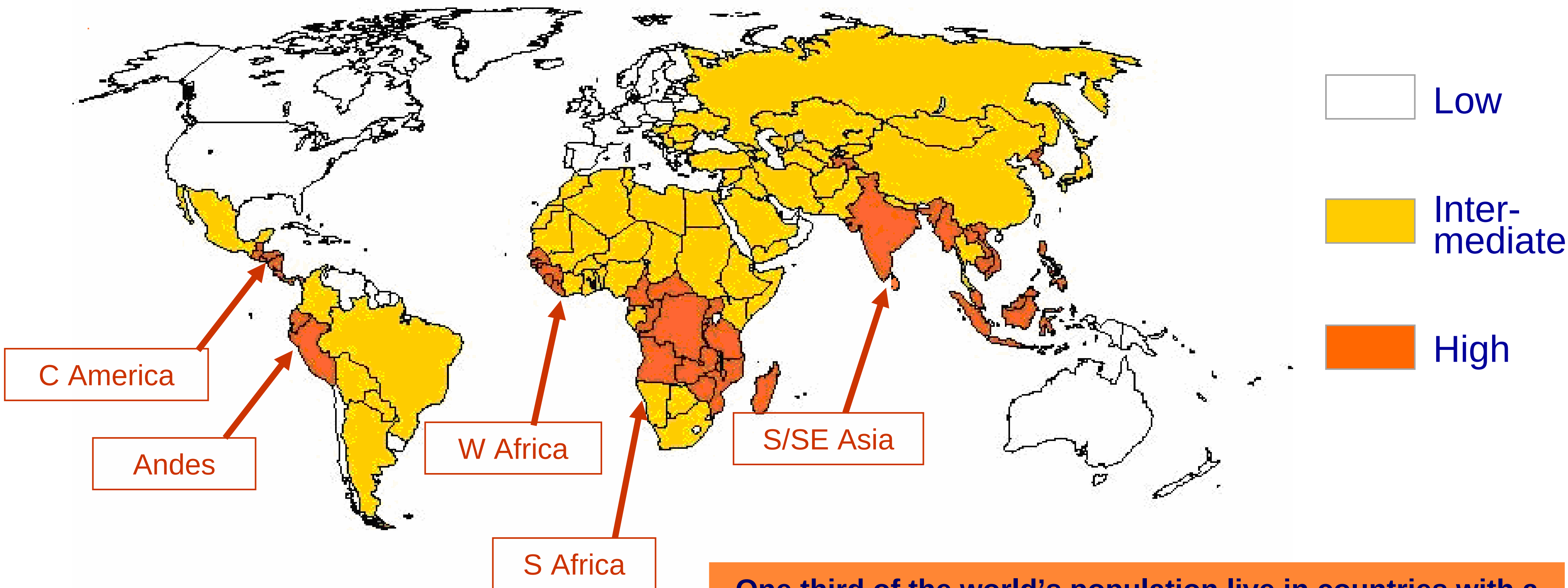
Importance of Zinc in Health

- Zinc participates in all major biochemical pathways in body
- Plays both catalytic and structural role (> 100 enzymes require zinc for catalytic function)
- Deficiency impairs multiple functions especially important for cells with rapid turnover
  - **Immune system**
  - **Intestinal mucosa**
- Increased requirements during rapid growth
- Investment in Zinc programmes contribute to achieving MDG targets
- Zinc supplementation of HIV positive children reduces the risk of both diarrhea and pneumonia

Consequences of Zinc Deficiency

- Strong evidence of the contribution of zinc impaired growth-zinc deficiency (even mild to moderate deficiency) contributes to stunted growth, illness and child deaths (Rivera *et al*., 2003)
- Immuno-dysfunctions (susceptibility to infection (ARI, pneumonia and diarrhea), increased illness and child deaths
- Abnormal neuro-behavioral development-Poor cognitive and motor development (Black, 2003)
- Adverse pregnancy outcomes-Crucial to later development of young women, reducing child birth complications (DFID, 2003)
- Zinc deficiency contributes to approximately 800,000 child deaths per year.

Risk of zinc deficiency, based on absorbable zinc in food supply and prevalence of stunting



One third of the world's population live in countries with a high risk of zinc deficiency

Estimated under-5 preventable deaths with universal coverage of each intervention strategy

Intervention	Deaths (X10^3)	% deaths
Breastfeeding	**1301**	**13**
Insecticide-treated nets	**691**	**7**
Complementary feeding	**587**	**6**
Zinc (preventive suppl)	**459**	**5**
Clean delivery	**411**	**4**
Hib vaccine	**403**	**4**
Water, sanitation, hygiene	**326**	**3**
Ante natal steroids	**264**	**3**

Jones *et al*. Lancet 2003

Micronutrient Initiative

Copenhagen Consensus

The returns of investing in micronutrient programmes, among a list of 17 possible development investments, are second only to those of fighting HIV/AIDS. It is ranked above trade liberalization, malaria, and water and sanitation."

The Copenhagen Consensus of eminent economists, 2004

The results

Project rating		Challenge	Opportunity
Very good	1	Diseases	Control of HIV/AIDS
	2	Malnutrition	Providing micro nutrients
	3	Subsidies and trade	Trade liberalisation
	4	Diseases	Control of malaria
Good	5	Malnutrition	Development of new agricultural technologies
	6	Sanitation and water	Small-scale water technology for livelihoods
	7	Sanitation and water	Community-managed water supply and sanitation
	8	Sanitation and water	Research on water productivity in food production
	9	Government	Lowering the cost of starting a new business
Fair	10	Migration	Lowering barriers to migration for skilled workers
	11	Malnutrition	Improving infant and child nutrition
	12	Malnutrition	Reducing the prevalence of low birth weight
	13	Diseases	Scaled-up basic health services
Bad	14	Migration	Guest-worker programmes for the unskilled
	15	Climate	"Optimal" carbon tax
	16	Climate	The Kyoto protocol
	17	Climate	Value-at-risk carbon tax

Source: Copenhagen Consensus

Note: Some of the proposals were not ranked

Role of Zinc Administration in Prevention of Childhood Diarrhea and Respiratory Illnesses: A meta Analysis . J Paediatrics June 2007

Meta analysis data showed:

- Zinc suppl. 14% reduction in occurrence of diarrheal episodes
- 8% reduction in occurrence of respiratory illness
- Duration of suppl: >3months, doses 15-140mg/week

Why are we doing so little to prevent zinc deficiency?

- **Zinc deficiency is difficult to detect:**
  - No perfect indicator of deficiency
  - Symptoms are non-specific
- **Therefore, Indirect indicators are used to estimate zinc deficiency such as:**
  - Food balance sheet data (FAO)- amount of absorbale zinc in national food supply
  - Absorbable zinc:
  - Prevalence of childhood stunting (WHO, DHS)

- **New Recommendations for the Assessment of Population Zinc Status**
  - **WHO / UNICEF / IAEA / IZiNCG**

- **Serum zinc concentration - best biomarker**
- **Dietary assessment - risk of inadequate intake**
- **Childhood stunting - best functional indicator**

Why should we be doing something to prevent zinc deficiency?

Investment in Zinc programmes contribute to achieving MDG targets

✓**Eradicating extreme poverty and hunger -** Zinc promotes child growth decreasing the prevalence of underweight children

✓**Reducing child mortality -** Zinc can help reduce child deaths significantly. Zinc substantially reduces the rates of diarrhoea and pneumonia - the most common causes of death among children in developing countries

✓**Improving maternal health -** Adequate zinc and micronutrient status is an important requirement to ensure maternal health and reduce maternal mortality

✓**Combat Infectious diseases -** zinc supplementation may reduce fatalities from these diseases

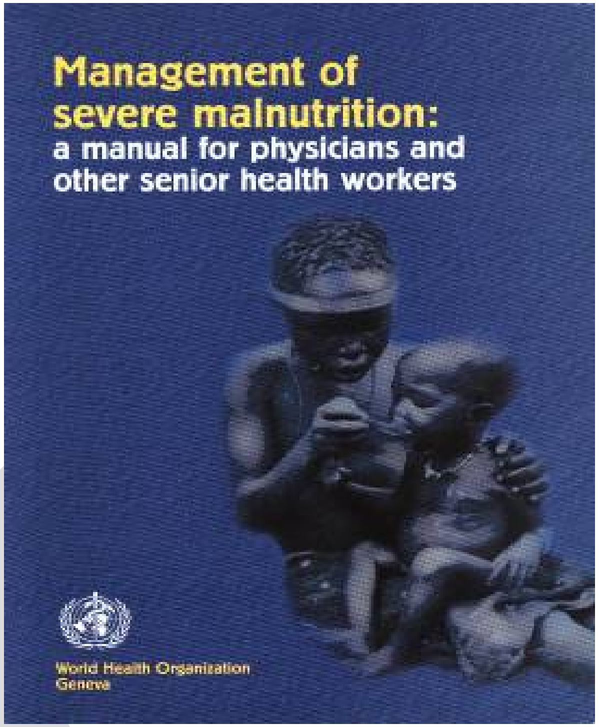
Adequate levels of zinc are essential for child survival and healthy development.
Zinc interventions will prevent 459 thousand deaths.

Main strategies

- Supplementation
- Fortification
- Dietary Diversification

Supplementation recommended for…

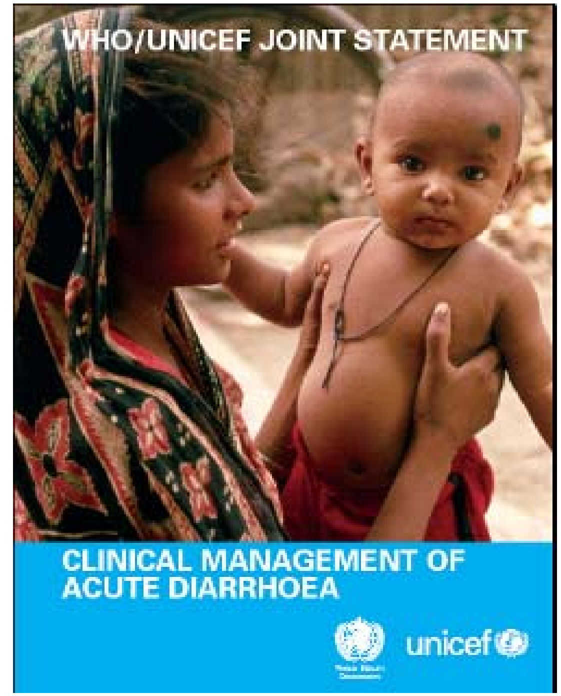
- **Treatment of severe protein-energy malnutrition**
  - incorporated into usual treatment regimen to provide twice age-specific RDA/day
- **Duration? - not specified part of the mineral mix**
- **Clinical management of diarrhea - recommendations available at: www.who.int/child-adolescent-health**



Supplementation recommended for…

WHO/UNICEF joint statement (2004)

Treatment of diarrhea - twice age-specific RDA/day (10-20 mg) X 10-14 day distributed with ORS



Fortification

- Addition of a nutrient(s) to a food, beverage, or condiment to enhance the overall nutritional quality of the diet
- Centralized, community and household fortification
- A few countries have flour fortification laws – Nigeria (flour, oil, sugar), South Africa (flour) and Zambia (flour, sugar) have fortification legislation
- Several countries are planning to fortify in the near future - Malawi, Uganda, Kenya
- Commercially fortified foods, complementary foods

Commonly Fortified Foods

Food	Nutrient
Salt	Iodine, Iron, Fluoride
Wheat and Maize flours	Iron, Folic Acid, B Vitamins, Vitamin A, Zinc
Cooking Oils and Fats	Vitamins A and D
Sugar	Vitamin A, Iron
Condiments (Sauces)	Iron
Milk	Vitamins A and D, Iron
Complementary Foods	Iron, Folic Acid, B Vitamins, Vitamin A, Zinc

Examples of Fortification Products

- **Fortified porridge, beverages**
- **Fortified spread**
- **“Sprinkles”**

Documented Evidence on the Strategies

- Studies indicate zinc fortification has the potential to increase total daily zinc absorption - populations who consume zinc fortified products will have improved zinc status
- Addition of Zinc to foods - negative impact not seen on absorption of other minerals
- Fortification a feasible strategy for zinc deficiency programmes

Fortification - Conclusions

- Fortification programmes recommended in high-risk populations to improve dietary zinc intakes (mass or targeted)
- Strategy considered safe and is promising
- Programme monitoring and evaluation strongly recommended

BUT…..

- Evidence regarding efficacy and effectiveness of zinc fortification programmes still incomplete
- Complementary foods - to date no positive effect seen on indicators of young children zinc status, growth or other zinc related functional responses
- Studies on both efficacy and effectiveness of fortified food products, including fortified complementary foods to improve zinc status are needed

Dietary Diversification to Improve Zinc Intake

- Exclusive breast feeding (first 6 months) and appropriate complementary feeding
- Agricultural interventions - Increasing the production and consumption of foods high in zinc
- Food processing to reduce dietary phytate content
- Increasing the intake of foods known to enhance absorption of zinc

Breastfeeding and Complementary Feeding

- Exclusive breastfeeding for birth till 6 months of age
- Breastfeeding provides infants with the zinc requirements
- Complementary feeding - introduction at 6 months of age, it should be safe with continued breastfeeding till the age of 2
- To ensure zinc requirements are met - infants should eat a variety of foods that include animal source foods
- The following should be taken into account for effective complementary feeding practices to achieve the desired impact
  - ✓ **Feeding practices, food choices and availability and cost of food**
  - ✓ **Nutrient quality of the food**
  - ✓ **Nutrition education**

Agricultural Interventions

- **Increasing the production of and intake of animal products**
  - ✓ Production of livestock such as poultry, goats, sheep- consumption should be encouraged, there is a tendency to rear these animals only for their monetary value and not nutritional value
  - ✓ Intake of these products would also provide other vitamins and minerals
- **Aquaculture strategies**
  - ✓ An alternative strategy especially when religious and ethnic believes discourage the consumption of meat and poultry
- **Promotion of indigenous zinc rich foods**
  - ✓ Identifying and encouraging increased consumption of foods known to have high zinc content

Methods of Food Processing

Why do we need to process some cereals and legumes? Phytate inhibits the absorption of iron and zinc

- Fermentation - induces phytate hydrolysis and decrease its inhibitory effect on zinc absorption
- Soaking - phytate is water soluble, soaking accelerate the leaching out of the phytate into the water
- Germination (malting) - promotes endogenous phytase activity in some cereals and legumes

Increasing Intake of Foods known to Enhance Absorption of Zinc

- Increasing intake of animal source protein as they increase zinc as well as non bioavailable (non heme) iron absorption
- The enhancing effect is attributed to certain chemicals (amino acids, peptides) released during the digestion of animal protein

Advantages of Dietary Diversification

- Long-term, likely to be sustainable
- Addresses multiple nutrients simultaneously without risk of toxicity
- Once behaviour change is achieved, requires minimal inputs
- Several approaches available

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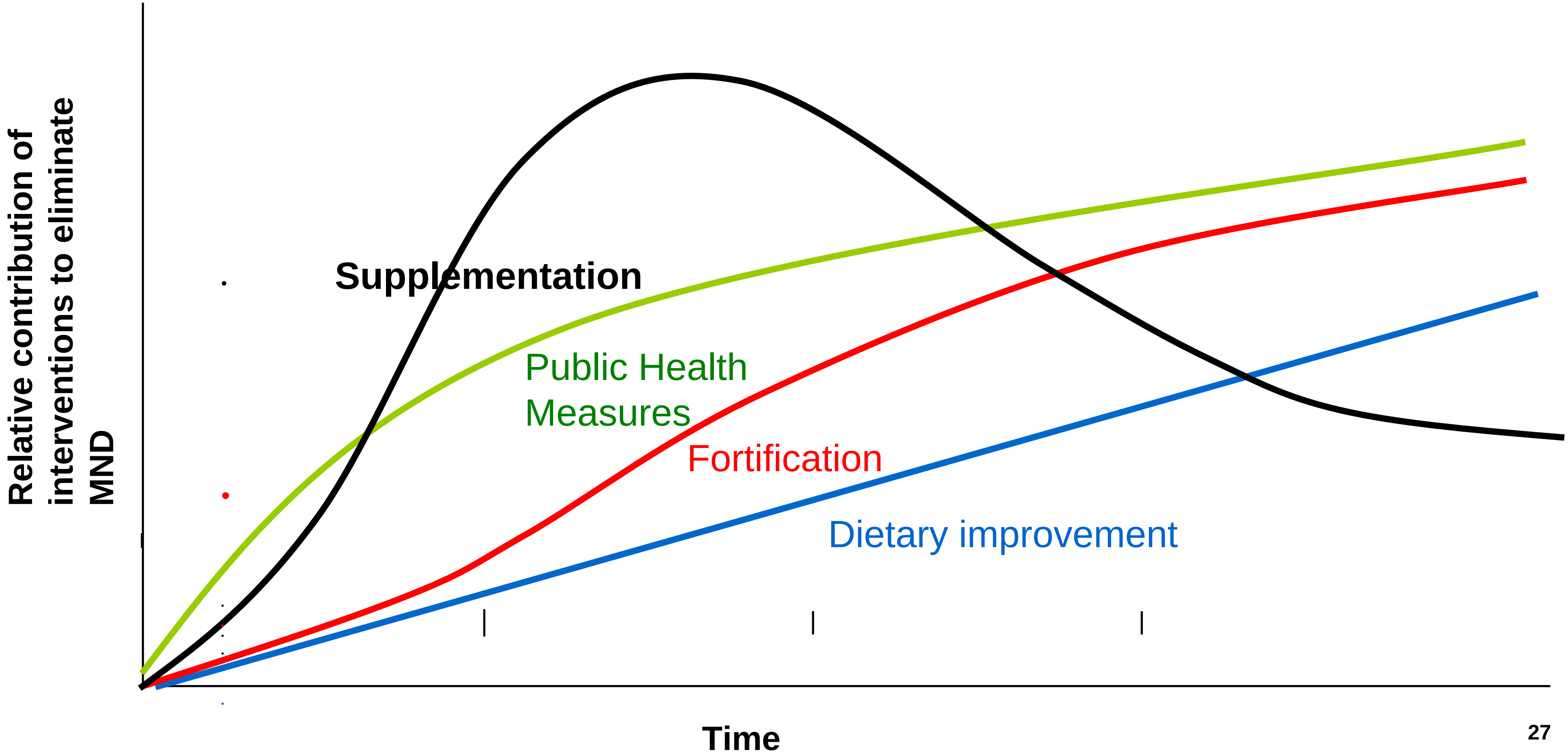
"…….. to highlight current and potential interventions – the roles of different approaches, their shortcomings, and the synergies that can be derived from them"



However…

- **To date, little has been done regarding specific food based interventions to evaluate efficacy, effectiveness, feasibility, cost-effectiveness, sustainability and the impact on the diets and nutritional status of at-risk populations**

Conclusions

- Zn is important for reduction of diarrhea, pneumonia prevalence
- Several intervention strategies are available to prevent zinc deficiency
- All strategies have their own strengths and weaknesses
- A combination of different strategies is needed to prevent zinc deficiency successfully in the long-term

Thank You

RESUMé : PROF DEMETRE LABADARIOS

Faculty of Health Sciences, University of Stellenbosch

Professor of Human Nutrition of the University of Stellenbosch University and the Tygerberg Academic Hospital

Fellow American College of Nutrition

Director: African Micronutrient Research Group

Director: Nutrition Support Team of the Tygerberg Academic Hospital

Director: Clinical Research Centre at the University of Stellenbosch (CNRC)

Director: Nutrition Information Centre at the University of Stellenbosch (NICUS)

Editor: South African Journal of Clinical Nutrition

African Editor: Nutrition: The International Journal of Basic and Applied Nutritional Sciences

Section Editor: Current Opinion in Clinical Nutrition and Metabolic Care

Editorial Boards: Public Health Nutrition, South African Journal of Enology and Viticulture, Clinical Nutrition, Journal of Pediatric Gastroenterology and Nutrition, J. Nutr. Health and Aging, American Journal of Dietetics Association.

President-Elect: South African Society of Parenteral and Enteral Nutrition

President: Information Technology in the Advancement of Nutrition in Africa (ITANA)

Zinc and nutrition in fertility / fertilization

Professor Demetre Labadarios

Human Nutrition
University of Stellenbosch and Tygerberg Academic Hospital, Tygerberg 7505
South Africa

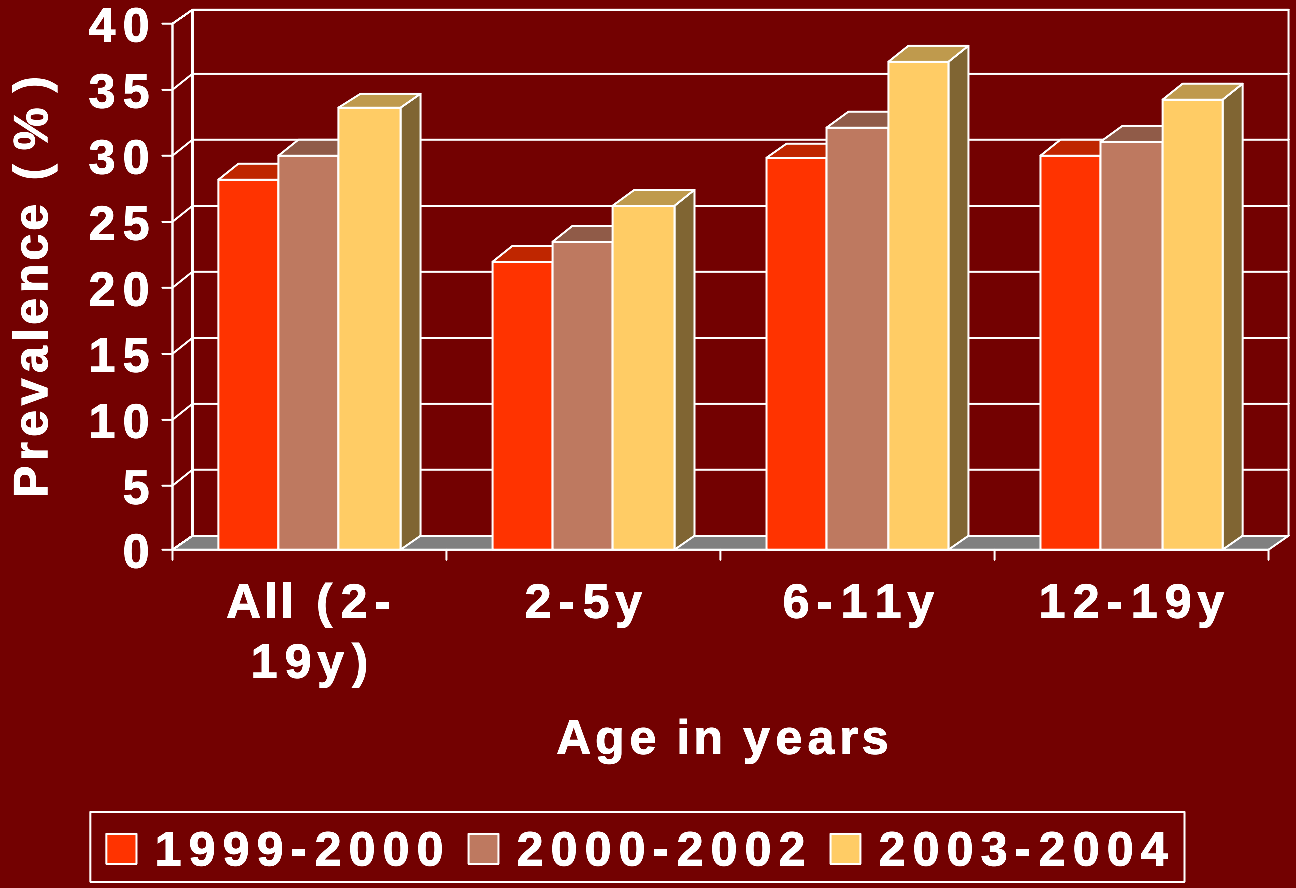
Zinc and nutrition in fertility/fertilization

- What is the evidence
- Selected gender based trends
- Share some ideas
- Practice point

Global transitions

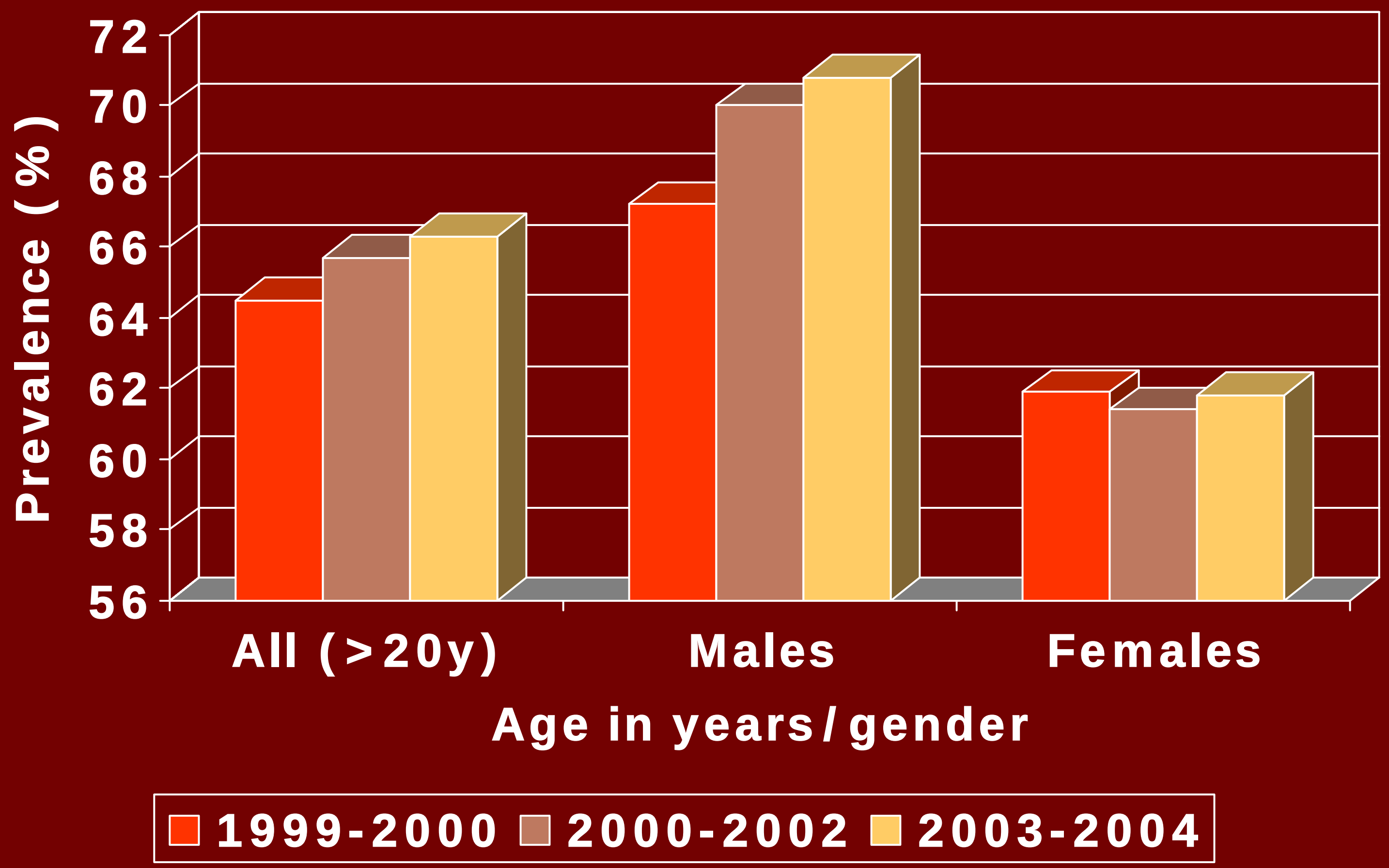
- Demographic
- Longer life expectancy
- Epidemiologic
- Infectious diseases replaced by chronic diseases
- Nutrition
- Grain based dietary patterns replaced with those of the western world
- Environmental
- Physical activity

Prevalence of overweight in children and adolescents in the USA 2006



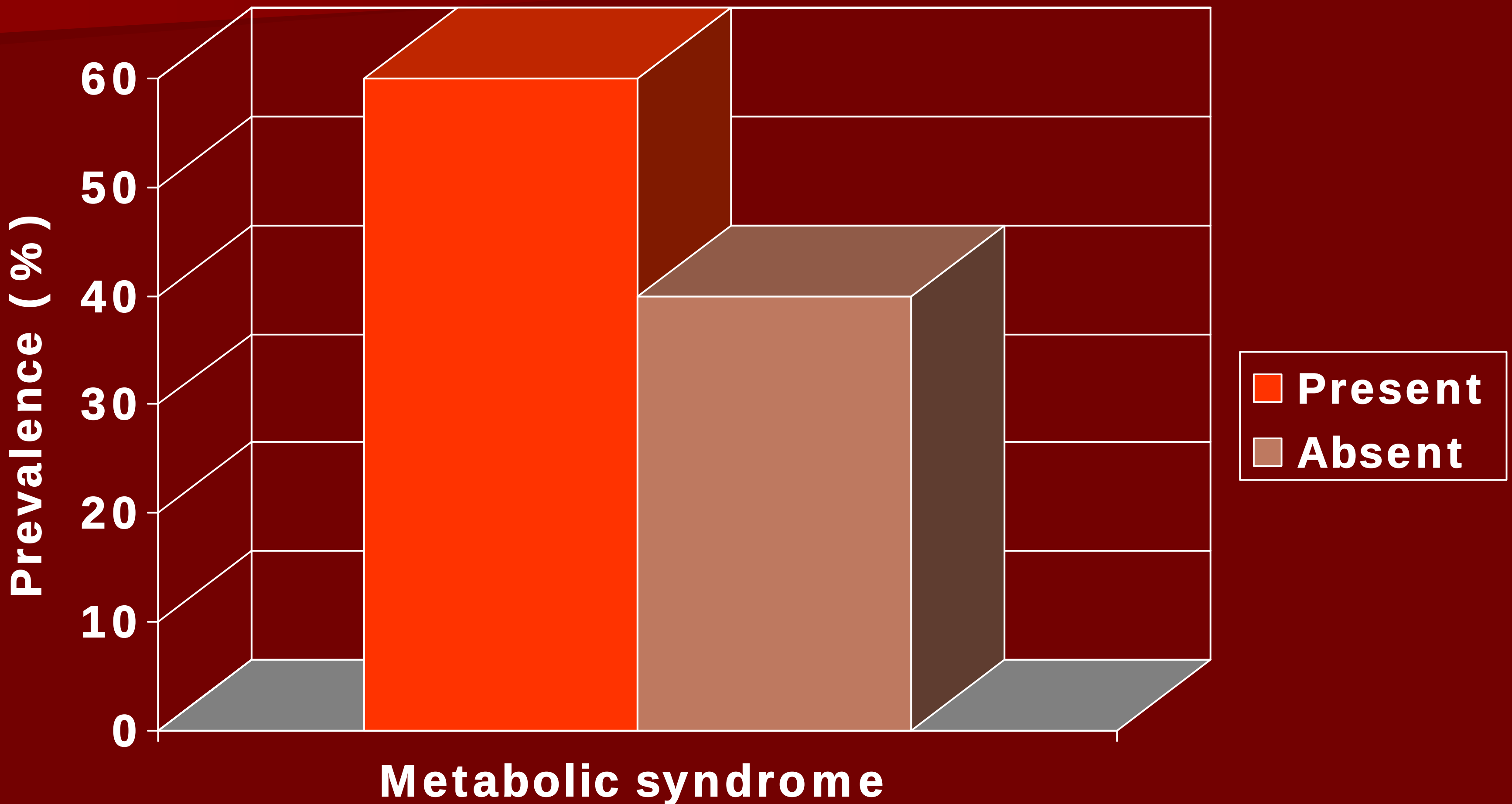
Ogden CL *et al*. 2006

Prevalence of adult overweight, obesity and extreme obesity in the USA 2006



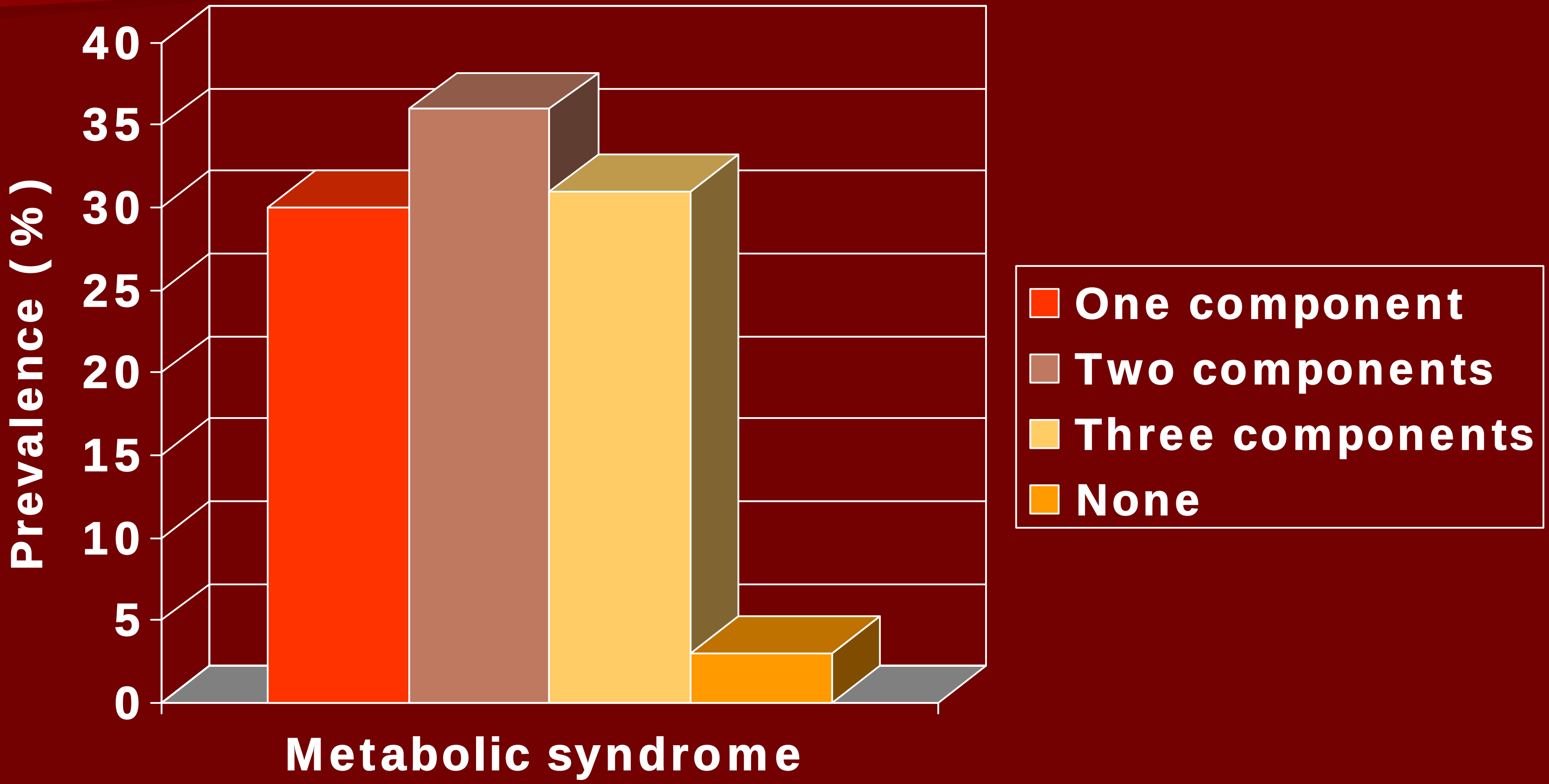
Ogden CL *et al*. 2006

Metabolic Syndrome: South African Blacks with CHD



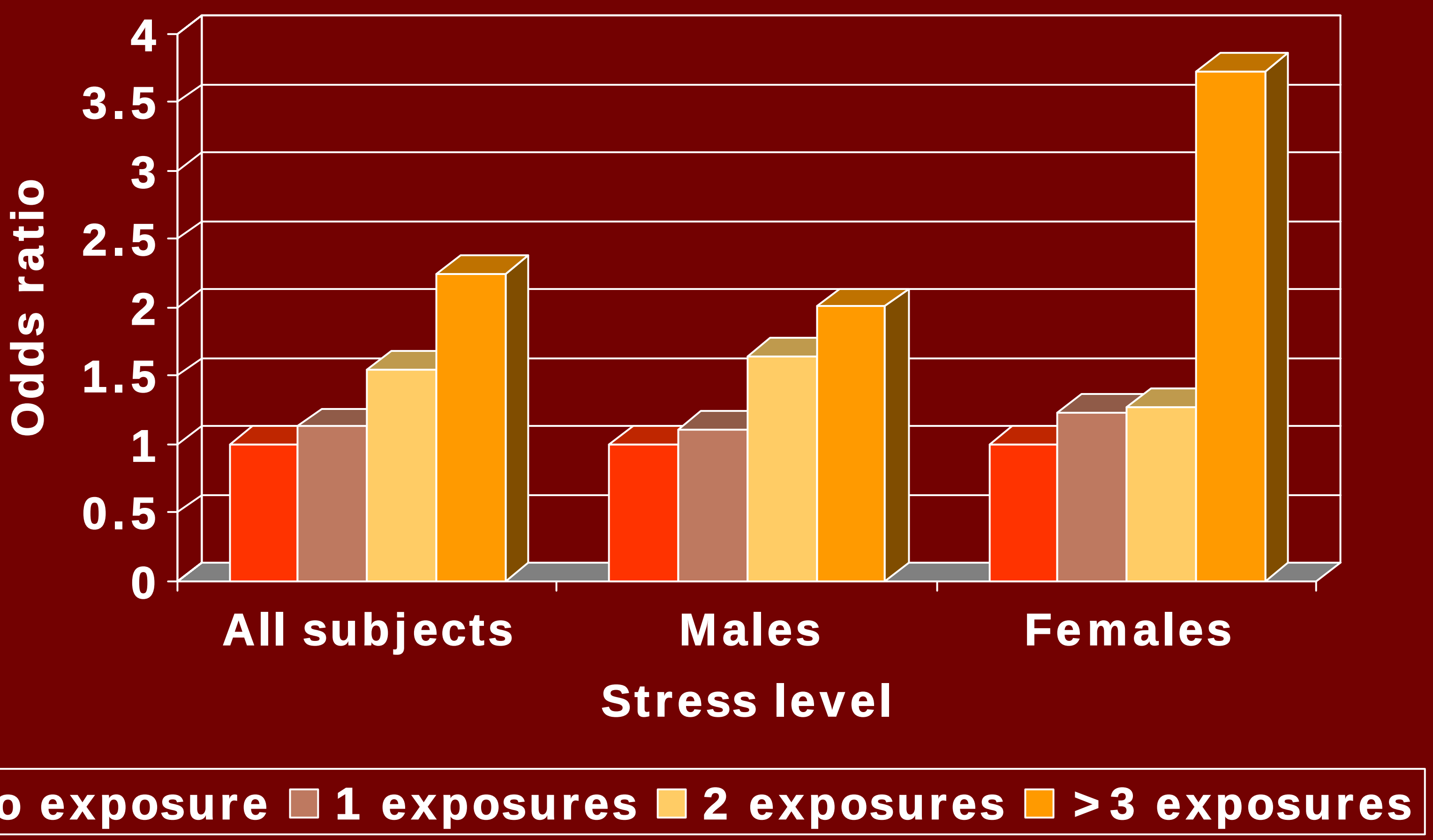
Ntyintyane LM, *et al*. 2006

Metabolic Syndrome: South African corporate executives



Ker JA, *et al*. 2007

Work stress and the metabolic syndrome



Chandola T, *et al*. 2006

Metabolic syndrome and total mortality

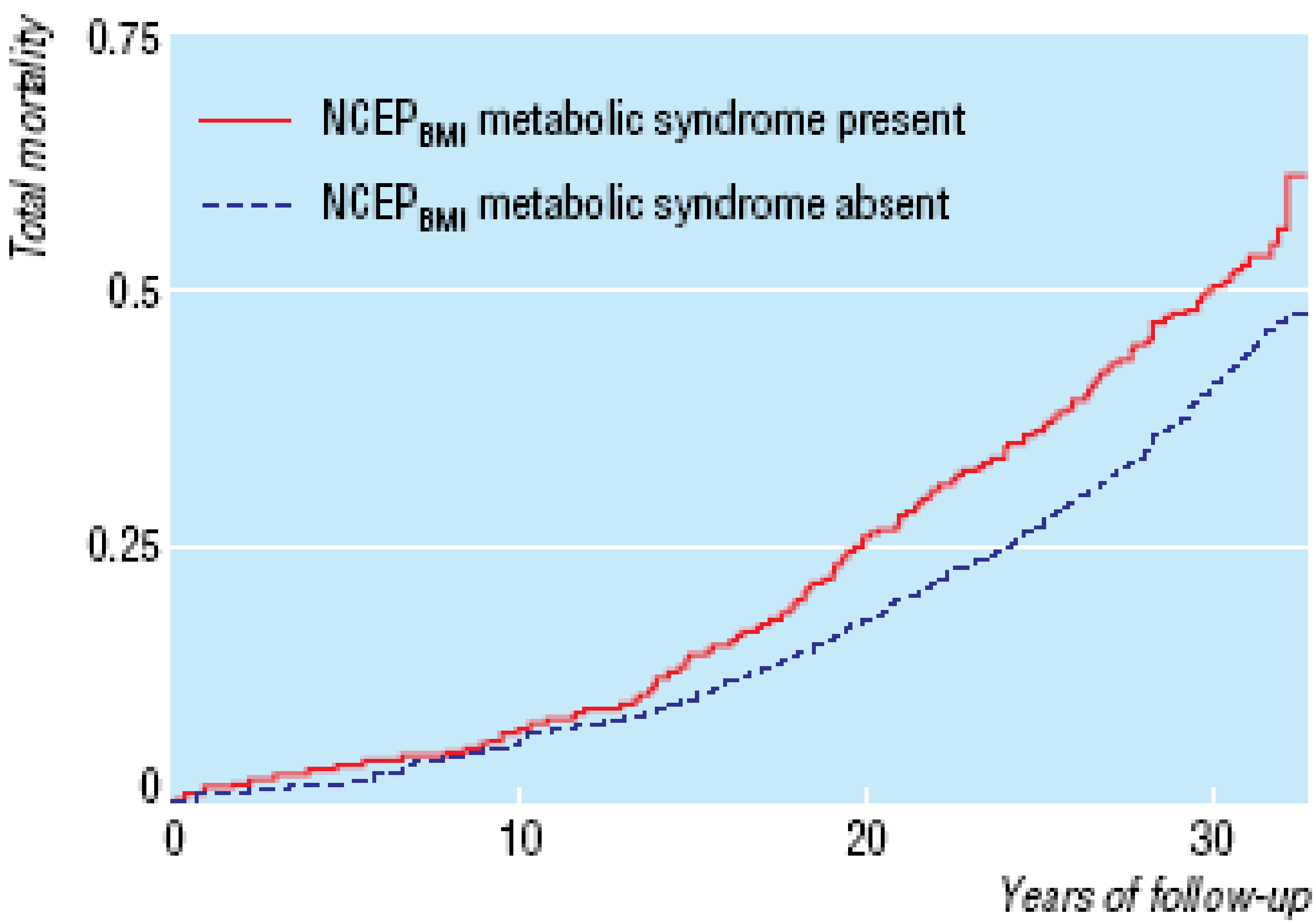
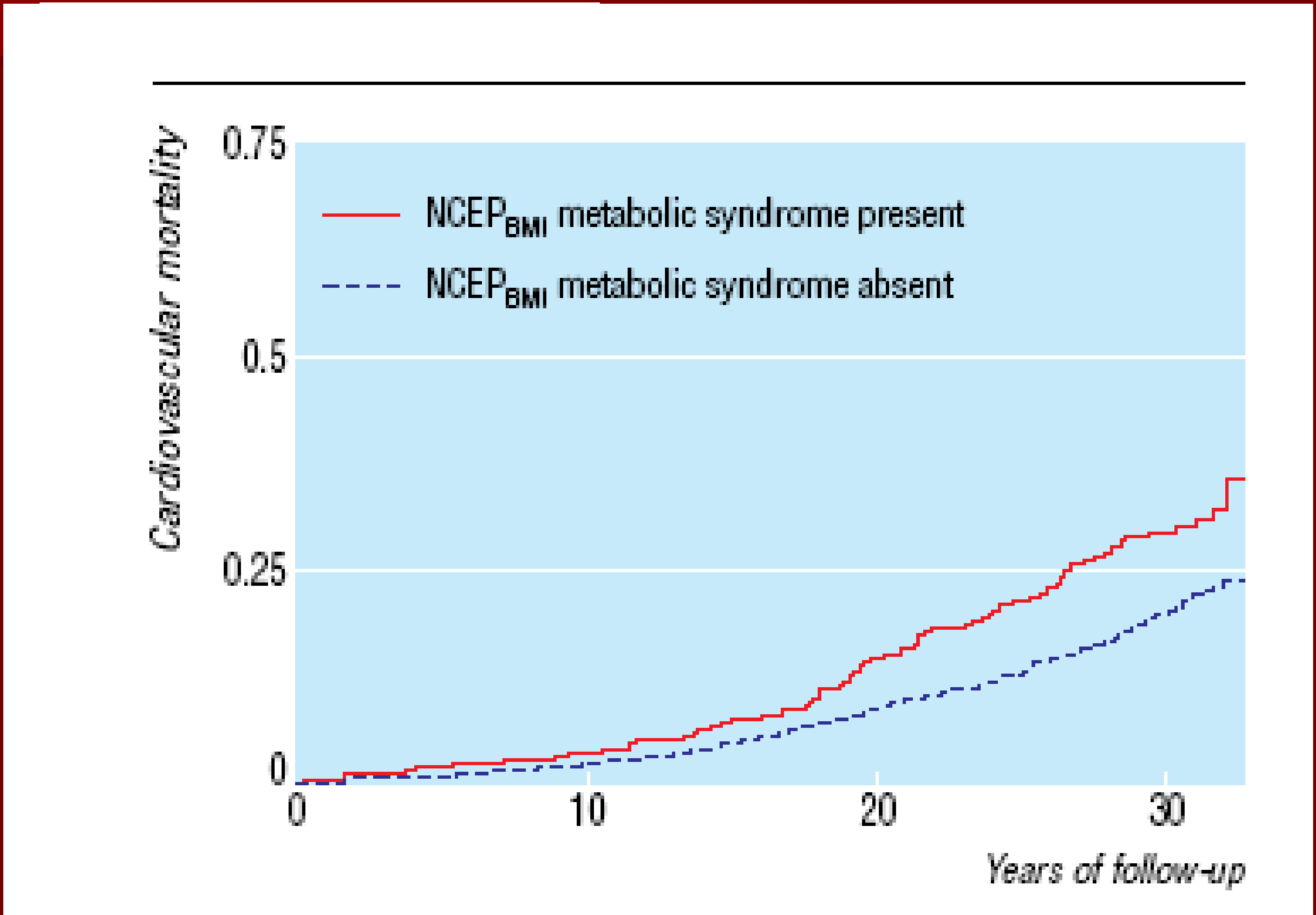


Fig 1 Total mortality by presence or absence of the metabolic syndrome

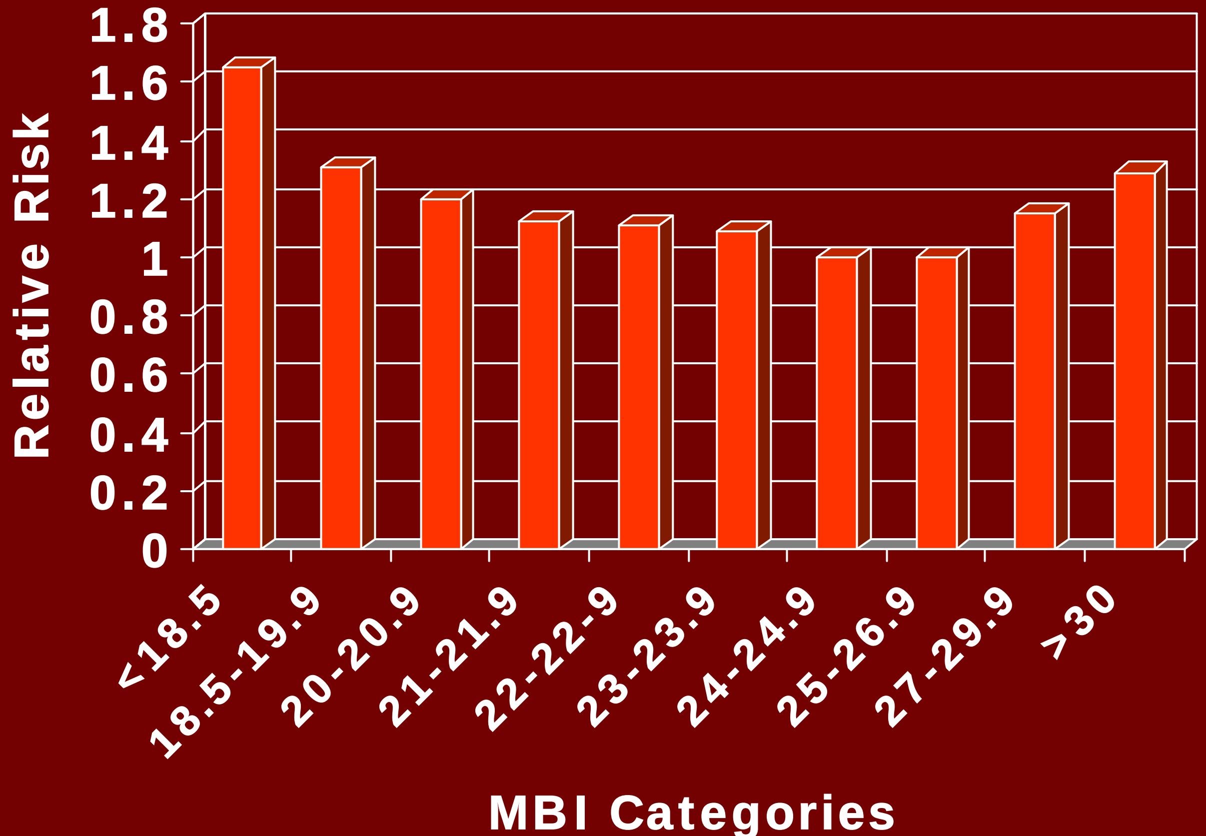
Sandstrom J *et al.* 2006

Metabolic syndrome and total mortality



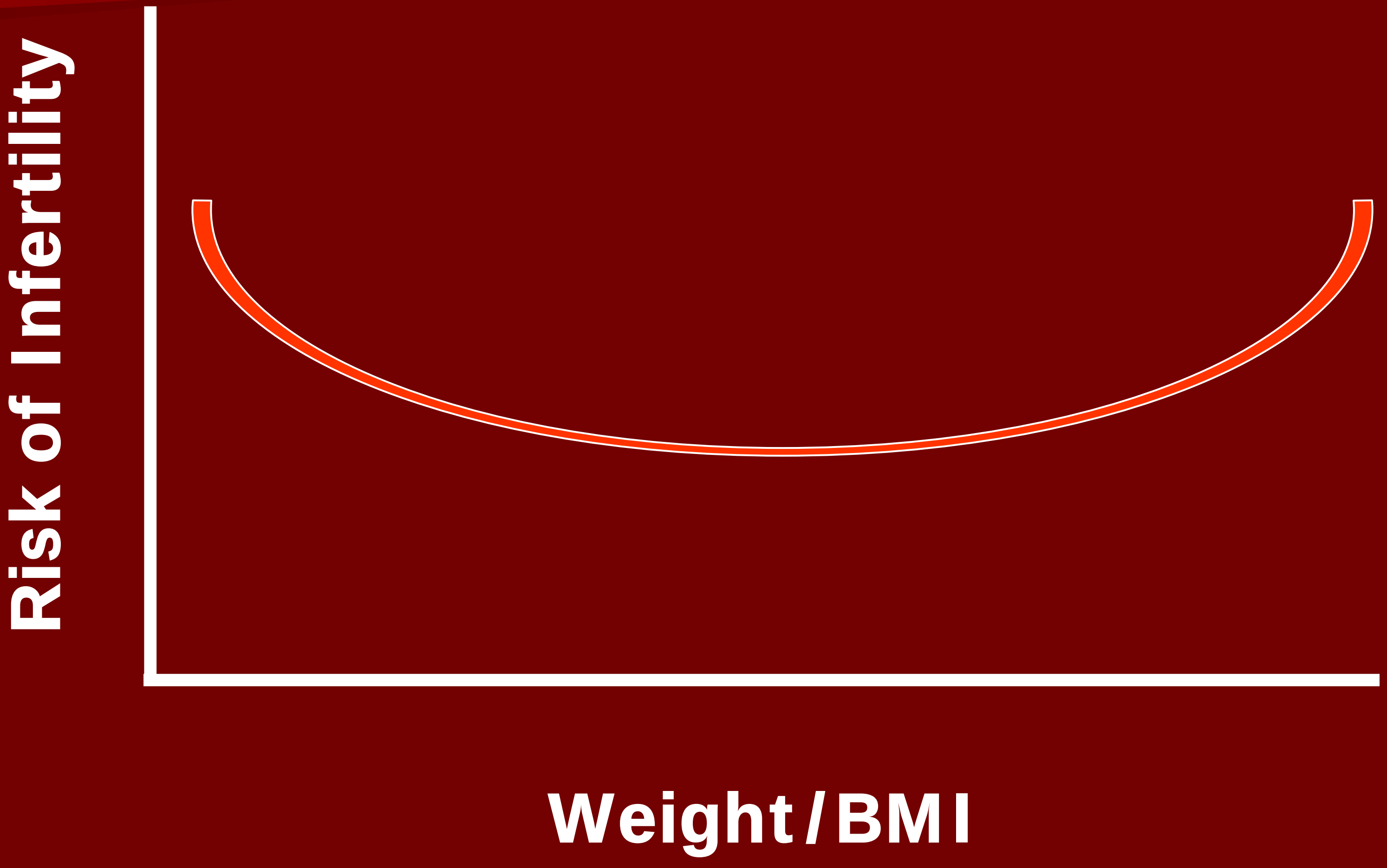
Sandstrom J *et al.* 2006

BMI and all-cause mortality in China

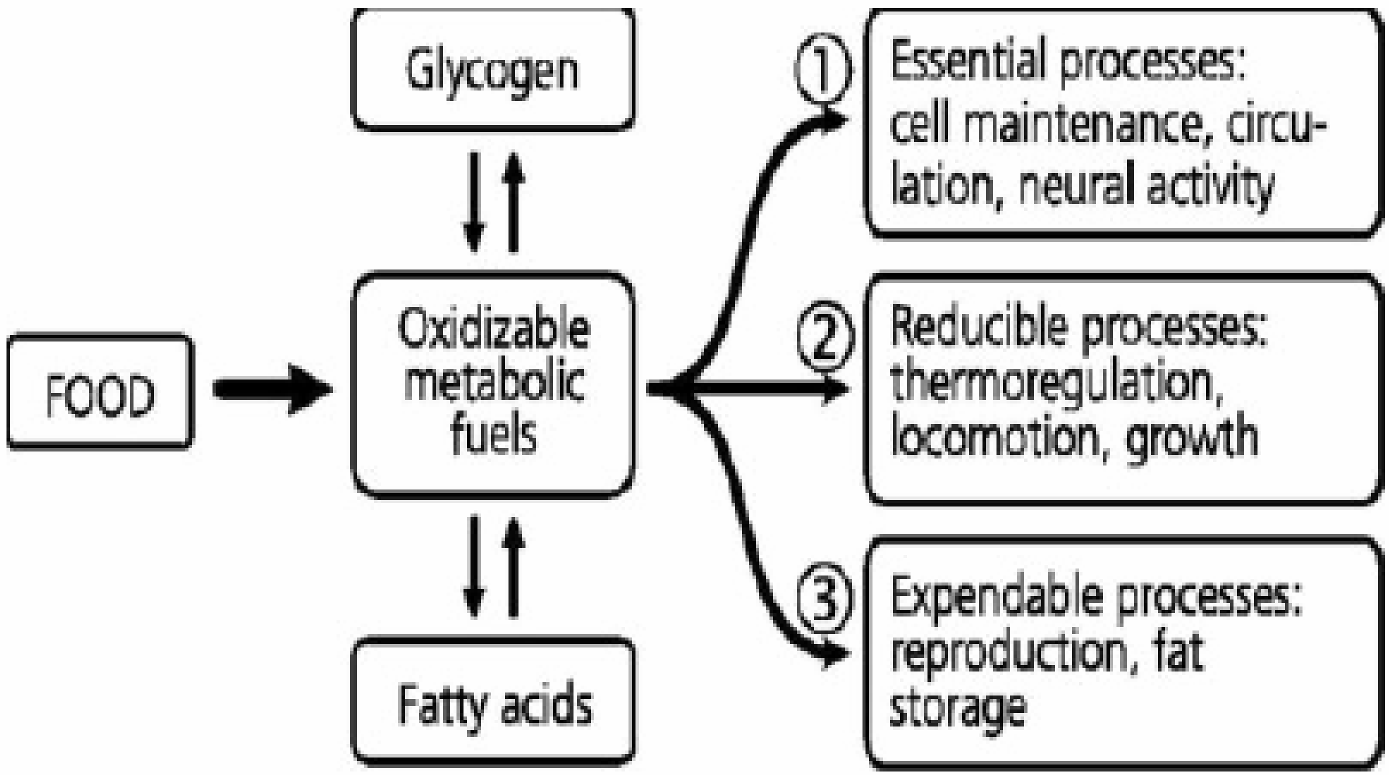


Gu D *et al*. 2006

Relationship between weight and fertility



Weight: Underweight



Wade and Jones 2004

Weight: Underweight

- Female reproductive system much more prone to energy balance disruption than the male
- Energy intake not fatness *per se* regulates reproductive function

Weight: Underweight

- Dutch famine 1944- 1945
- Eating disorders of today
- Nutrition influences ovulation, fertilization, implantation as well as early fetal development

Weight: Overweight/Obesity is a pro-inflammatory state

- Adipocytes are critical for health, apart from their role in fat storage
- Regulators of free fatty acid storage and oxidation in the adipocyte and the periphery are critical regulators of homeostasis

Greenberg AS *et al*. 2006

Weight: Overweight/Obesity is a pro-inflammatory state

- Adipocytes release hormones (leptin, resistin and Adiponectin) which in lean individuals modulate body fat mass
- In obesity adipocyte control mechanisms become dysfunctional, macrophages infiltrate adipose tissue and induce the inflammatory response

Greenberg AS *et al*. 2006

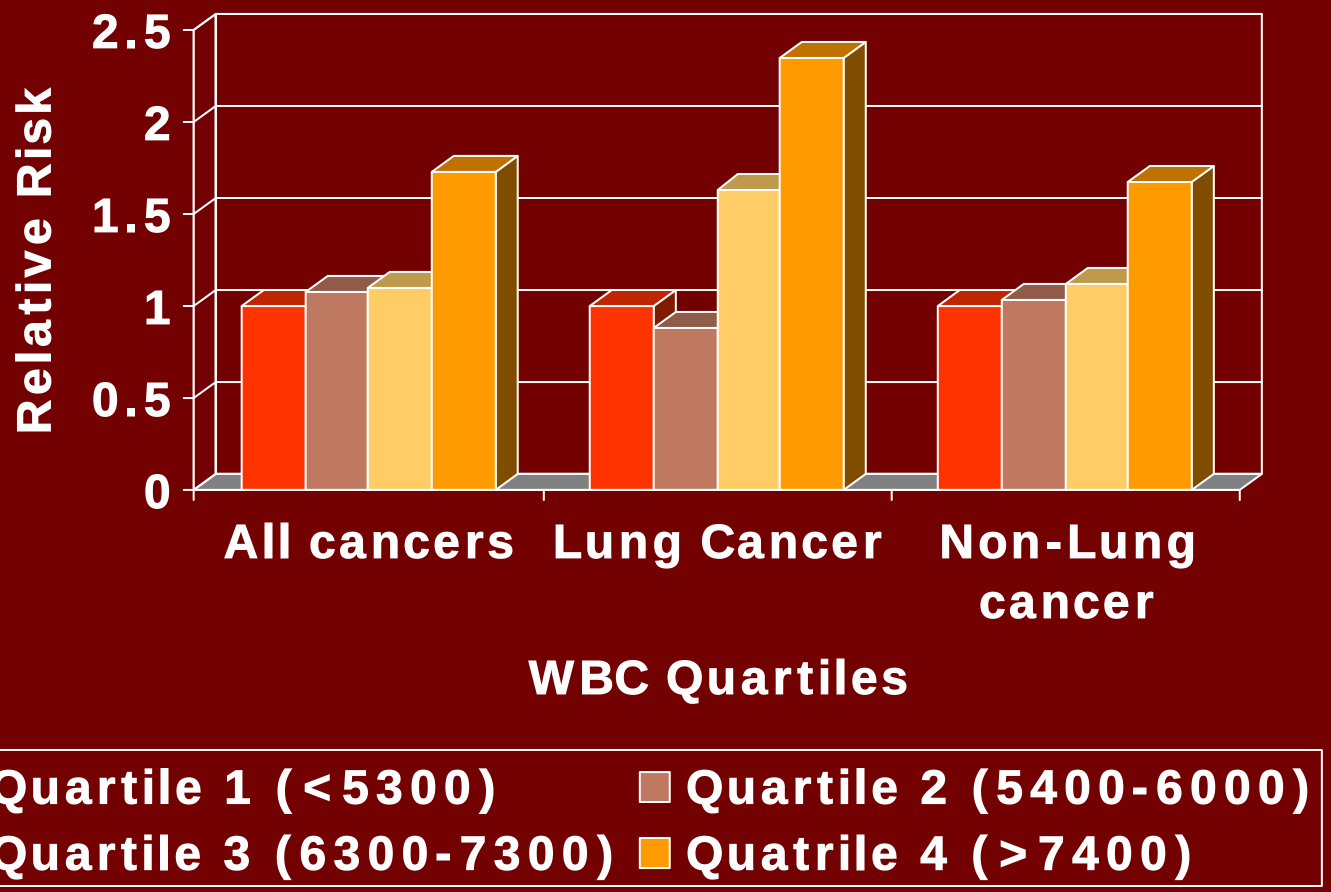
Role of inflammation in chronic disease

- Association of inflammatory markers (e.g. CRP) with an ever-increasing number of physical and mental illness/chronic diseases
- Associations reported with CVD, likelihood of disease in healthy people, CVD and non-CVD complications, likelihood of dying

Role of inflammation in chronic disease

- Associations being reported with other markers of inflammation, findings which change the interpretation of traditional investigations

White blood cell count and cancer mortality

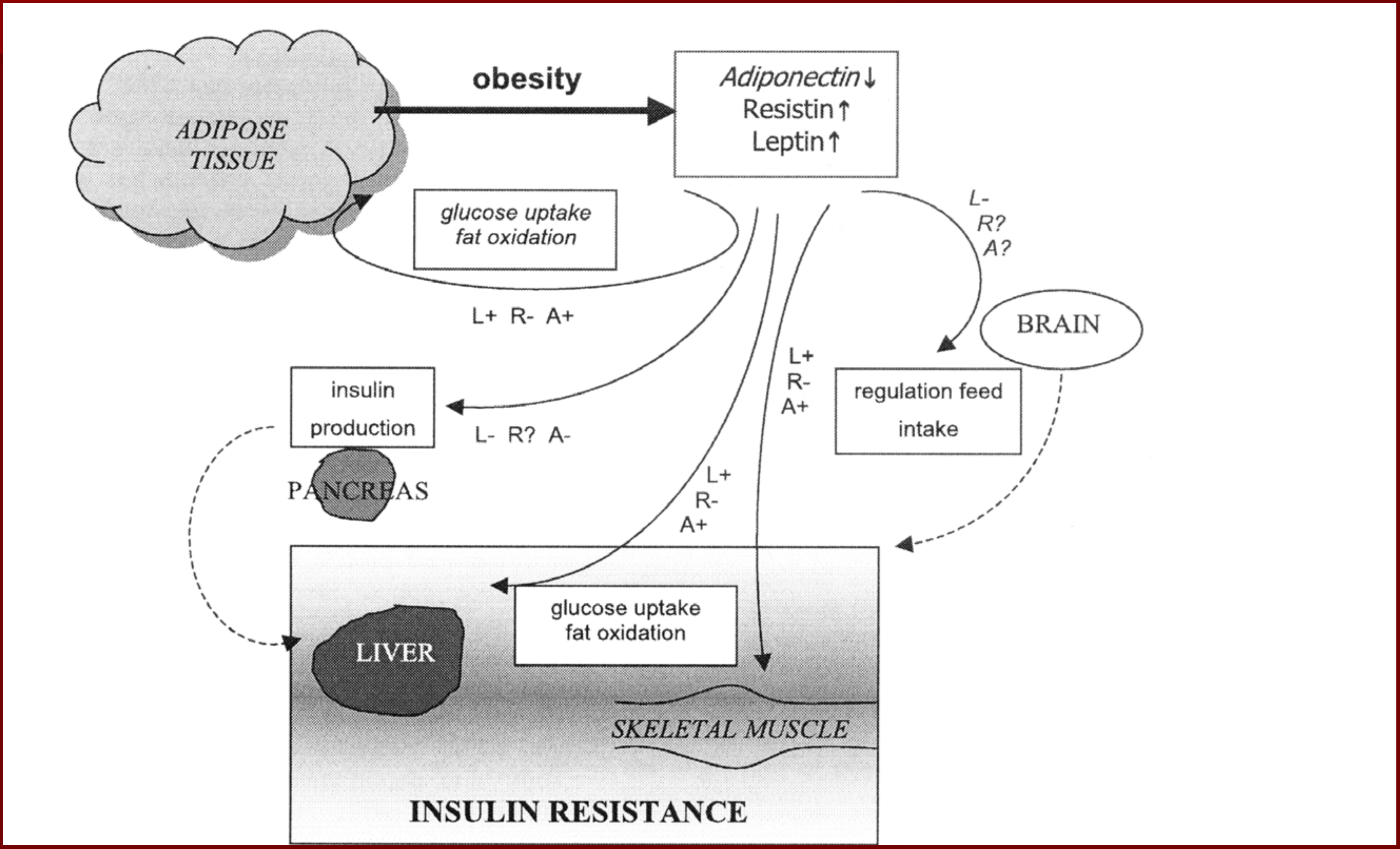


Shankar A, *et al*. 2006

Role of inflammation in reproduction

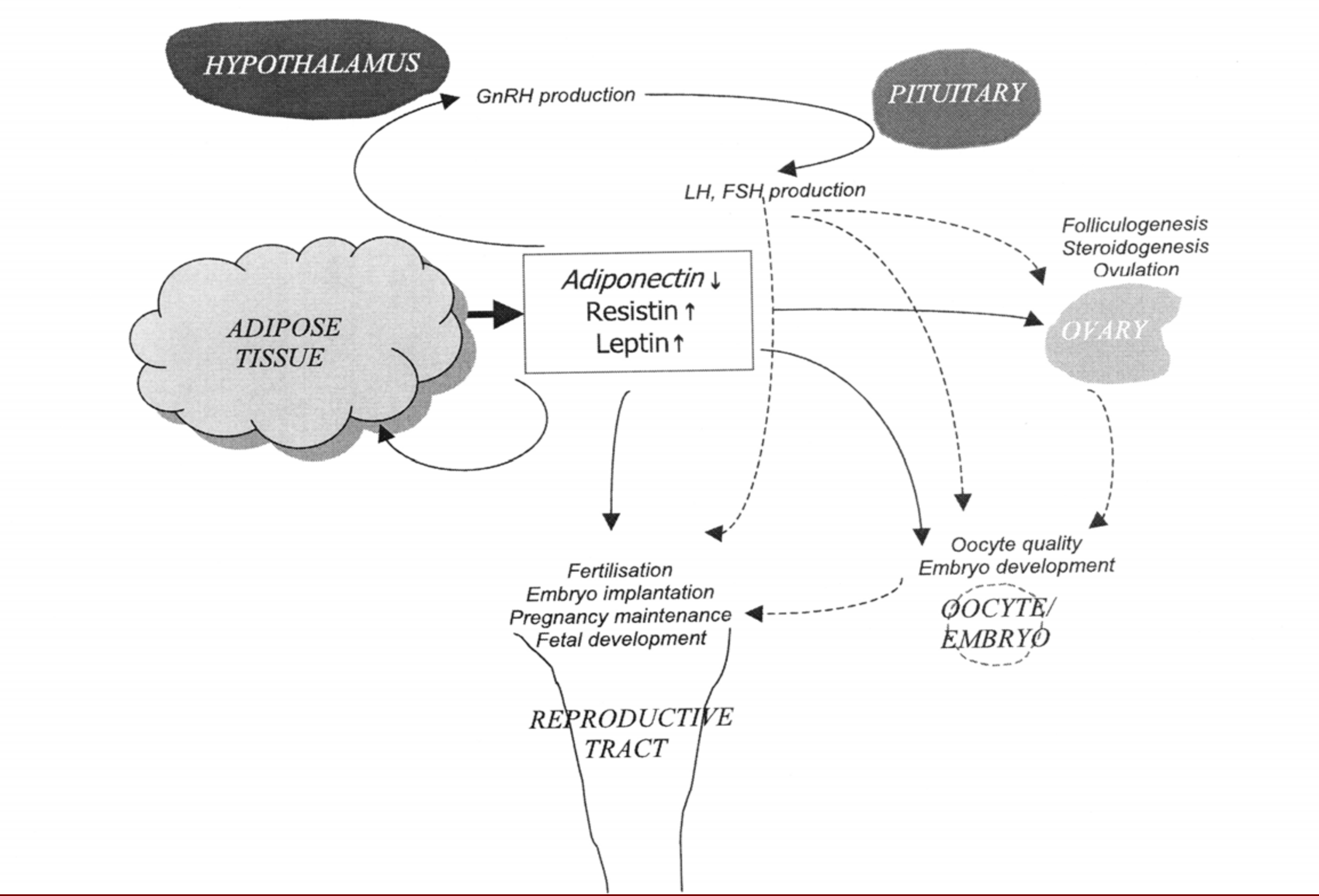
- Associations of inflammation and outcomes is determined by genetic variation
- Potential interactions being reported in reproduction

Weight: Overweight / Obesity is a pro-inflammatory state



Mitchell M, *et al.* 2005

Weight: Overweight / Obesity is a pro-inflammatory state



Mitchell M, *et al.* 2005

Negative effects of obesity on fertility: Women

- Precocious menarche
- Menstrual alterations (oligo-amenorrhea)
- Chronic oligo- or anovulation
- Relative hyperandrogenic state
- Pathophysiological implication in the PCOS
- Reduced rates of pregnancy after assisted reproductive technology

Pasquali R *et al*. 2006

Negative effects of obesity on fertility: Women

- Increased risk of abortion
- Increased risk of morbidity in obese pregnant women
- Preterm deliveries and increased fetal morbidity and mortality

Pasquali R *et al*. 2006

Negative effects of obesity on fertility: Men

- Hypotestosteronemia
- Hypogonadotropic hypogonadism (in massive obesity)
- Erectile dysfunction
- Reduced spermatogenesis (rare)

Pasquali R *et al*. 2006

POSSIBLE CAUSES OF FALLING SPERM COUNTS

- Increased scrotal temperature
  - tight-fitting clothing and briefs
  - Varicoceles are more common
- Environmental
  - Age
  - Increased pollution
  - Heavy metals (lead, mercury, arsenic)
  - Organic solvents
  - Pesticides (DDT, PCBs, DBCP)

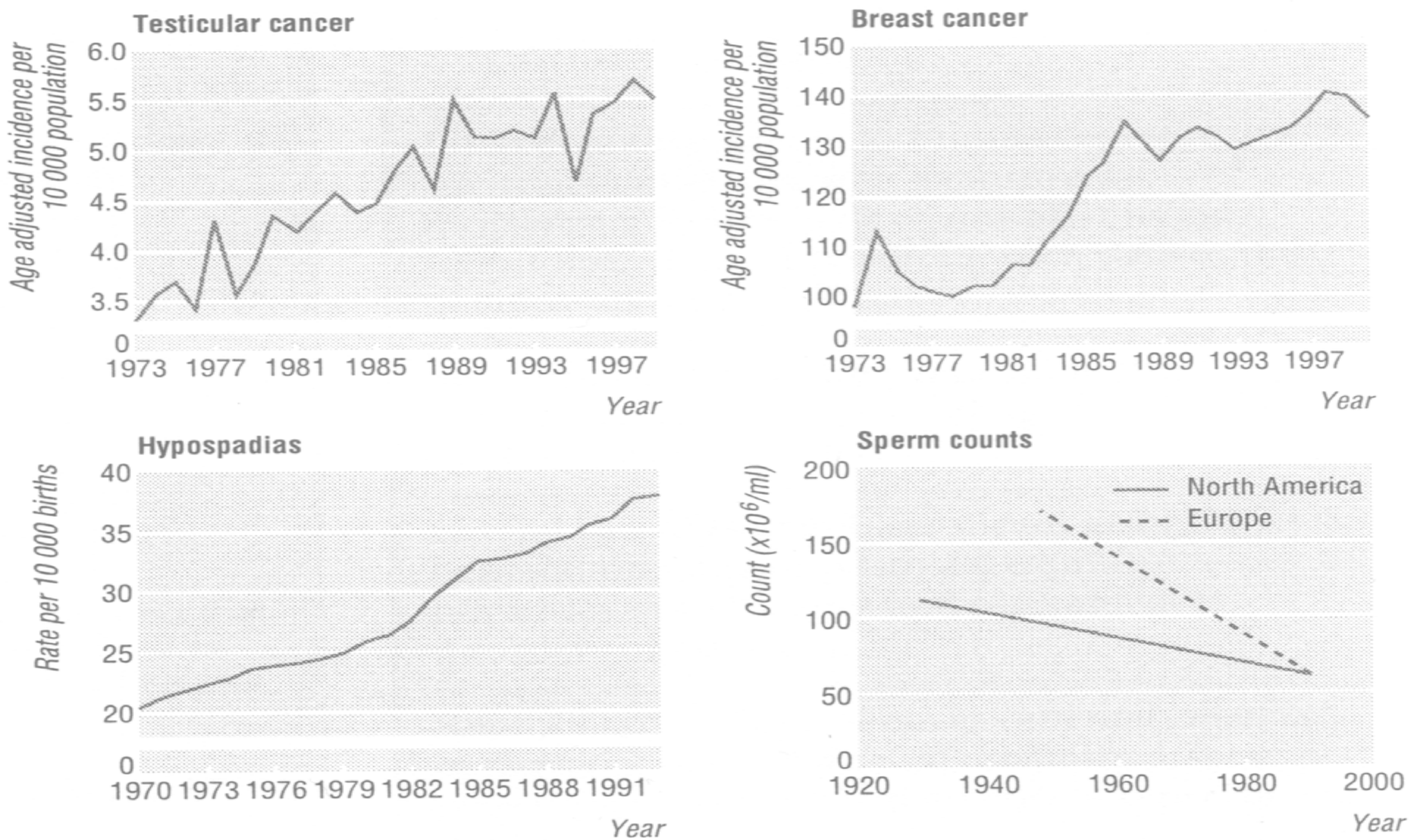
Murray MT *et al*. 1997

POSSIBLE CAUSES OF FALLING SPERM COUNTS

- Dietary
  - Increased saturated fats
  - Reduced intake of fruits, vegetables, and whole grains
  - Reduced intake of dietary fiber
  - Increased exposure to synthetic estrogens

Murray MT *et al*. 1997

Environment: Falling sperm counts



Sharpe RM *et al.* 2004

Environment: Falling sperm counts

- Little definitive data links human reproductive disorders or cancers with exposure to environmental synthetic chemicals; this may reflect difficulties in obtaining such data or the genuine absence of effects

Sharpe RM *et al*. 2004

Male Infertility: Causes

- Deficient sperm production
- Ductal obstruction
- Congenital defects
  - Postinfectious obstruction
  - Cystic fibrosis
  - Vasectomy
- Ejaculatory dysfunction
  - Premature ejaculation
  - Retrograde ejaculation

Murray MT *et al*. 1997

Male Infertility: Causes

- Coital disorders
  - Defects in technique
  - Premature withdrawal
  - Erectile dysfunction
- Disorders of accessory glands
  - Antisperm antibodies
  - Infection
  - Inflammation
  - Associated oxidant damage

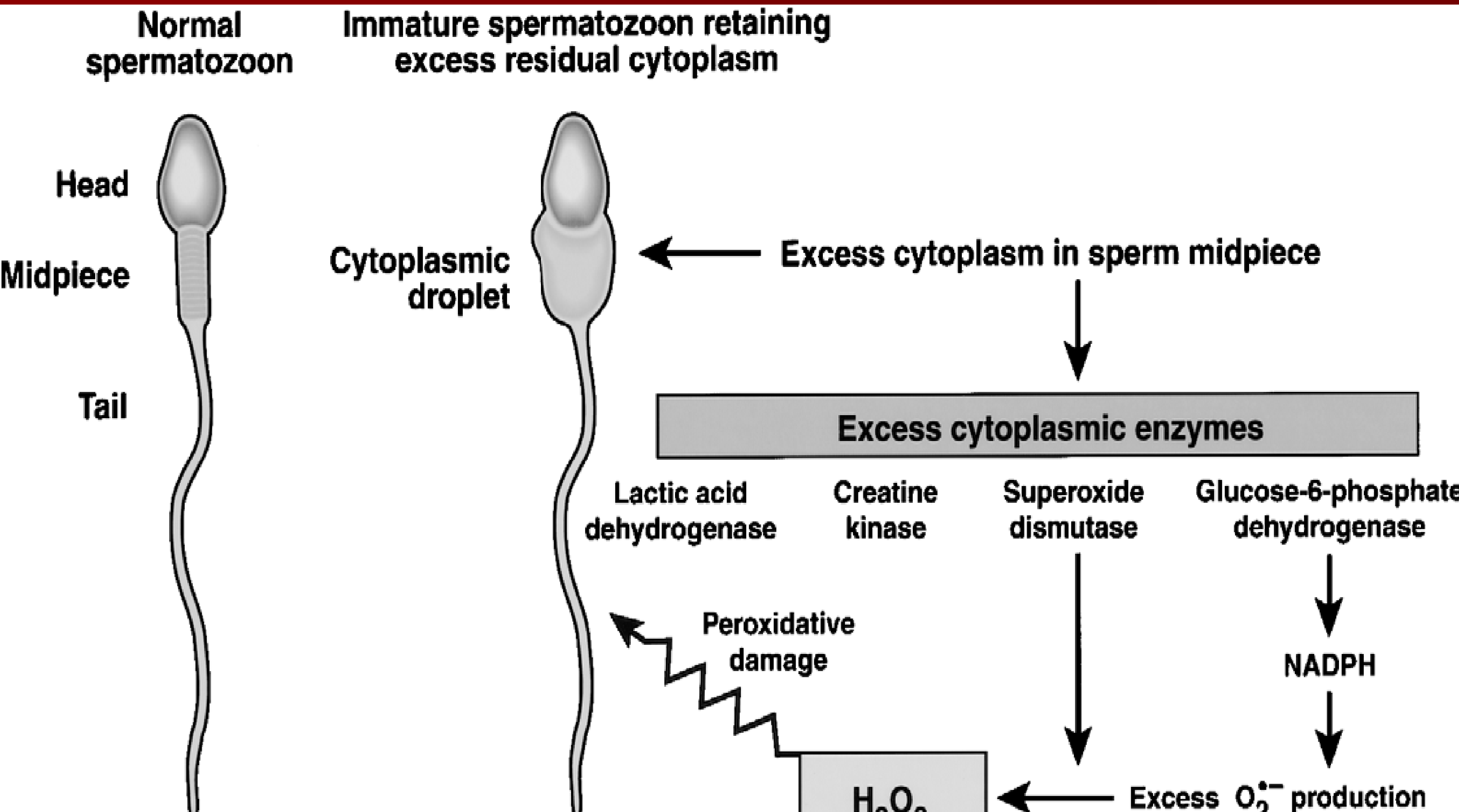
Murray MT *et al*. 1997

Male Infertility: Causes

- Coital disorders
  - Defects in technique
  - Premature withdrawal
  - Erectile dysfunction
- Disorders of accessory glands
  - Antisperm antibodies
  - Infection
  - Inflammation
  - Associated oxidant damage

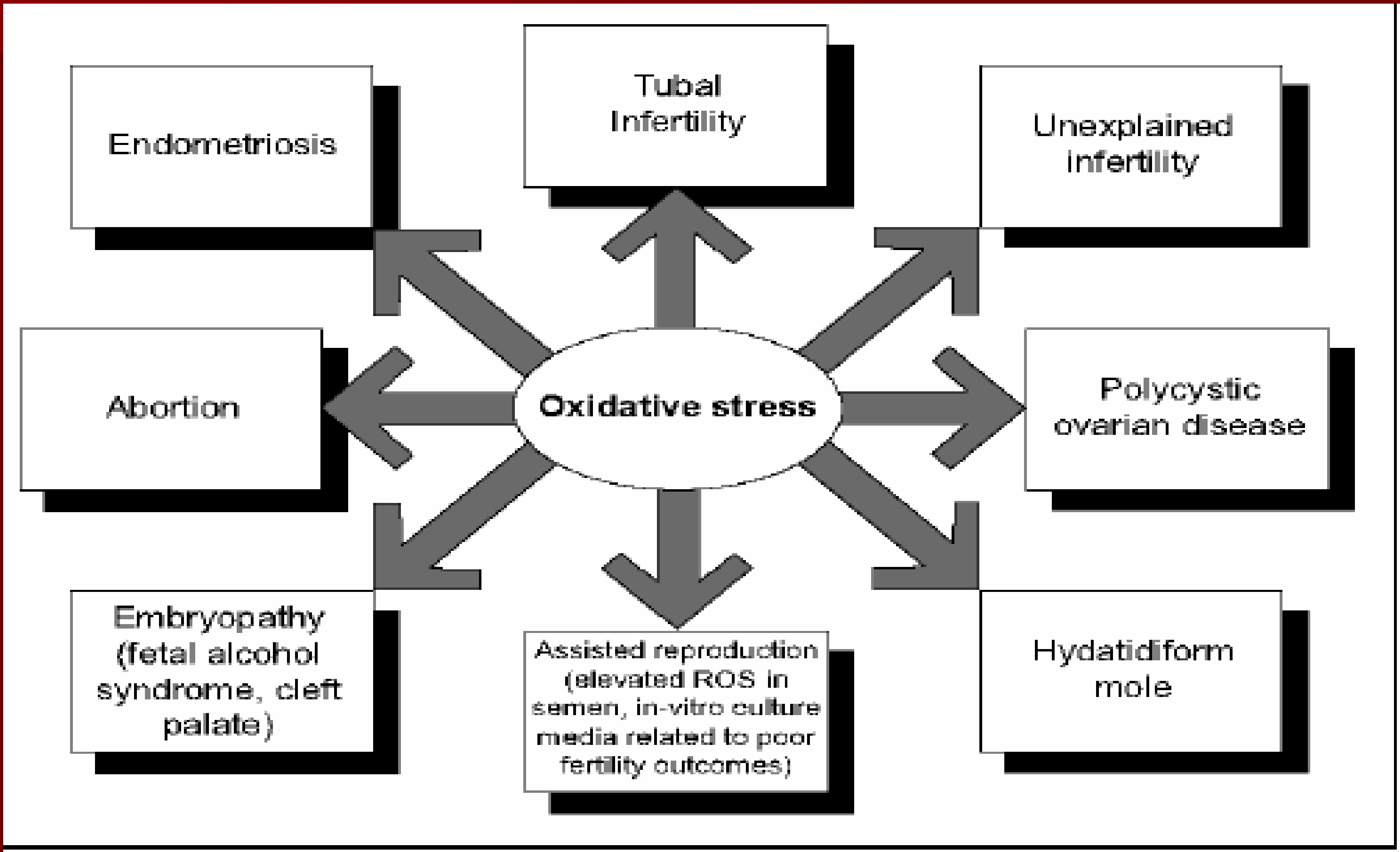
Murray MT *et al*. 1997

Male Infertility: Role of oxidants



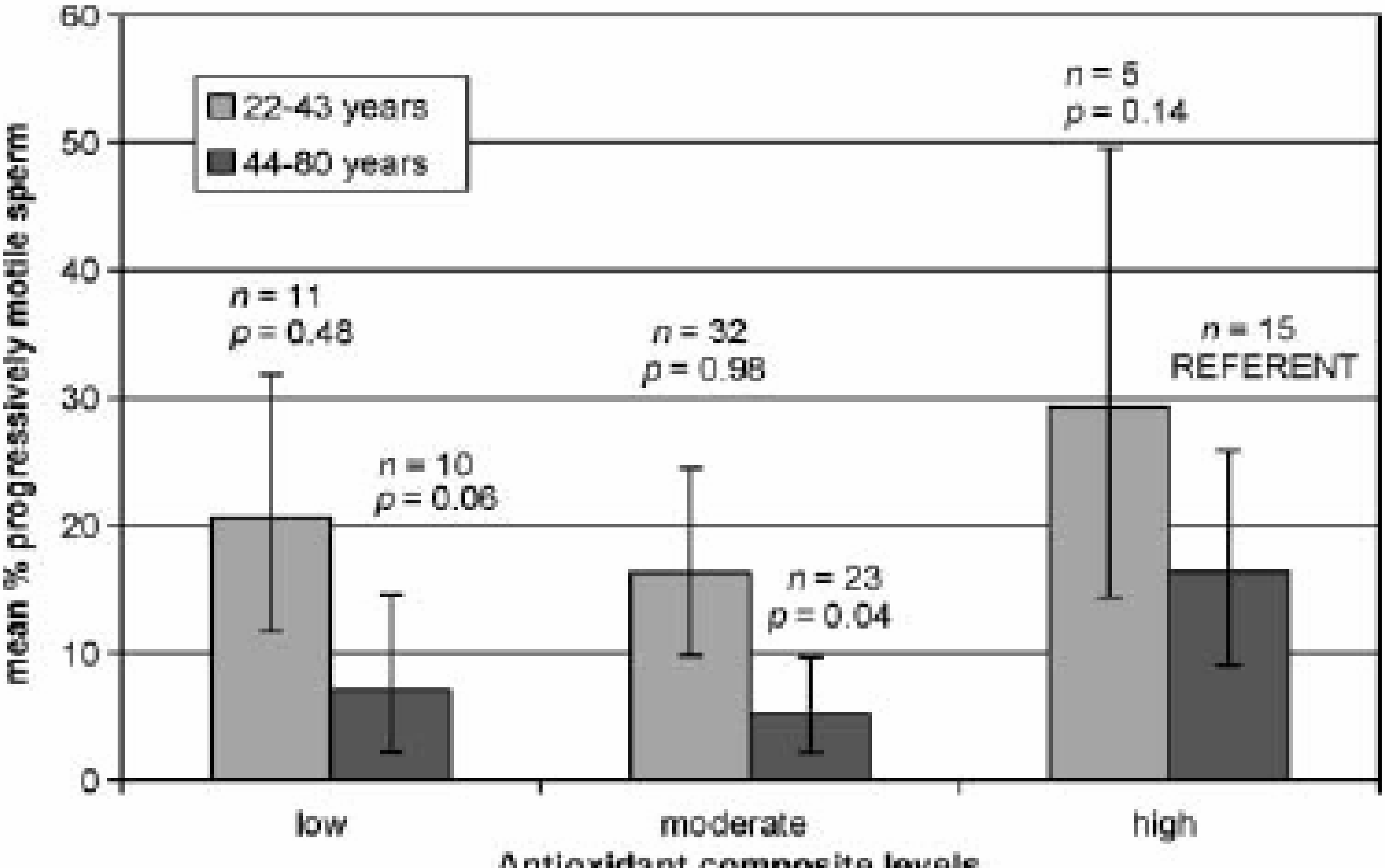
Agarwal A *et al.* 2002

Female Infertility: Role of oxidants



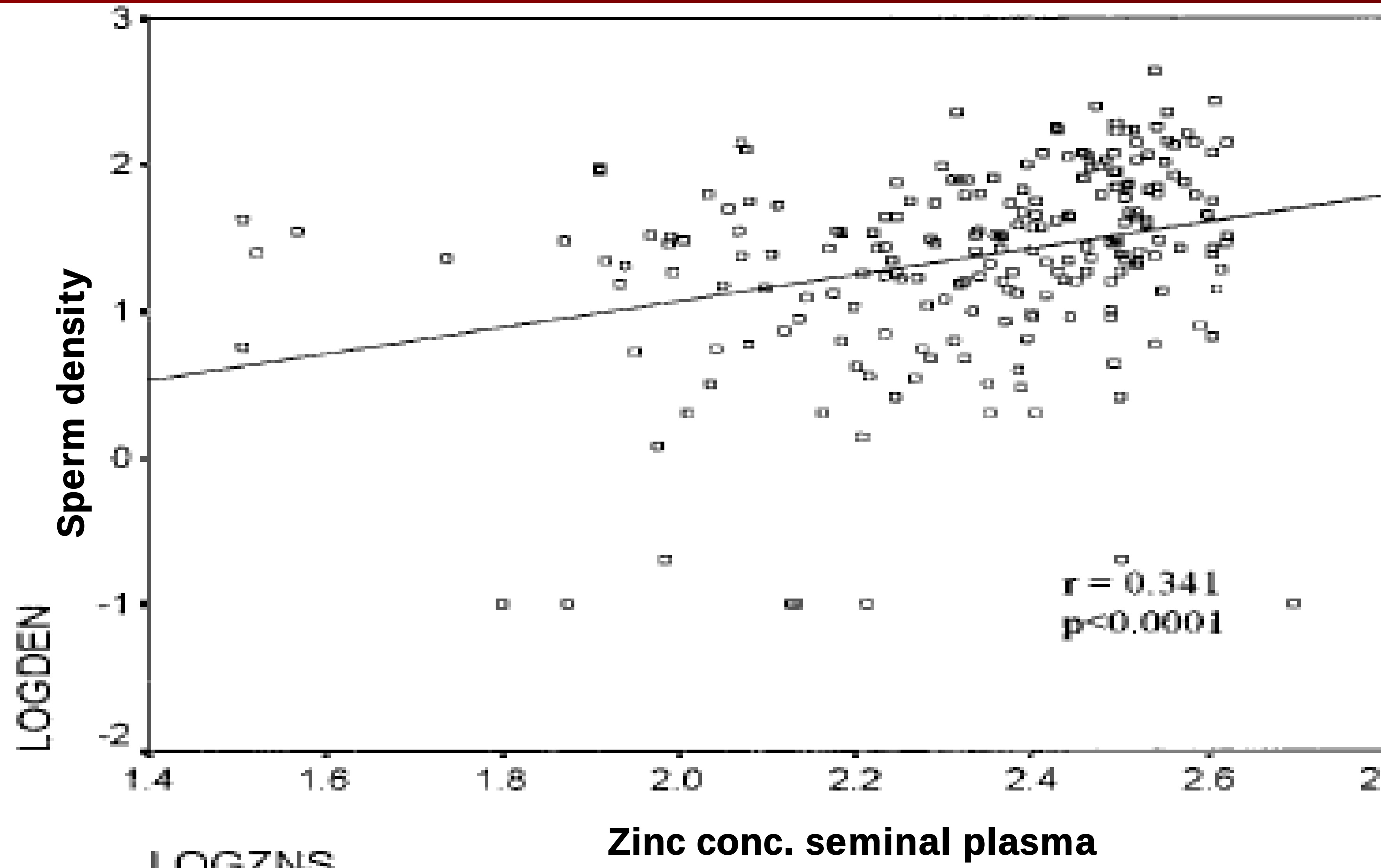
Agarwal A *et al.* 2006

Male Infertility: Role of antioxidant intake



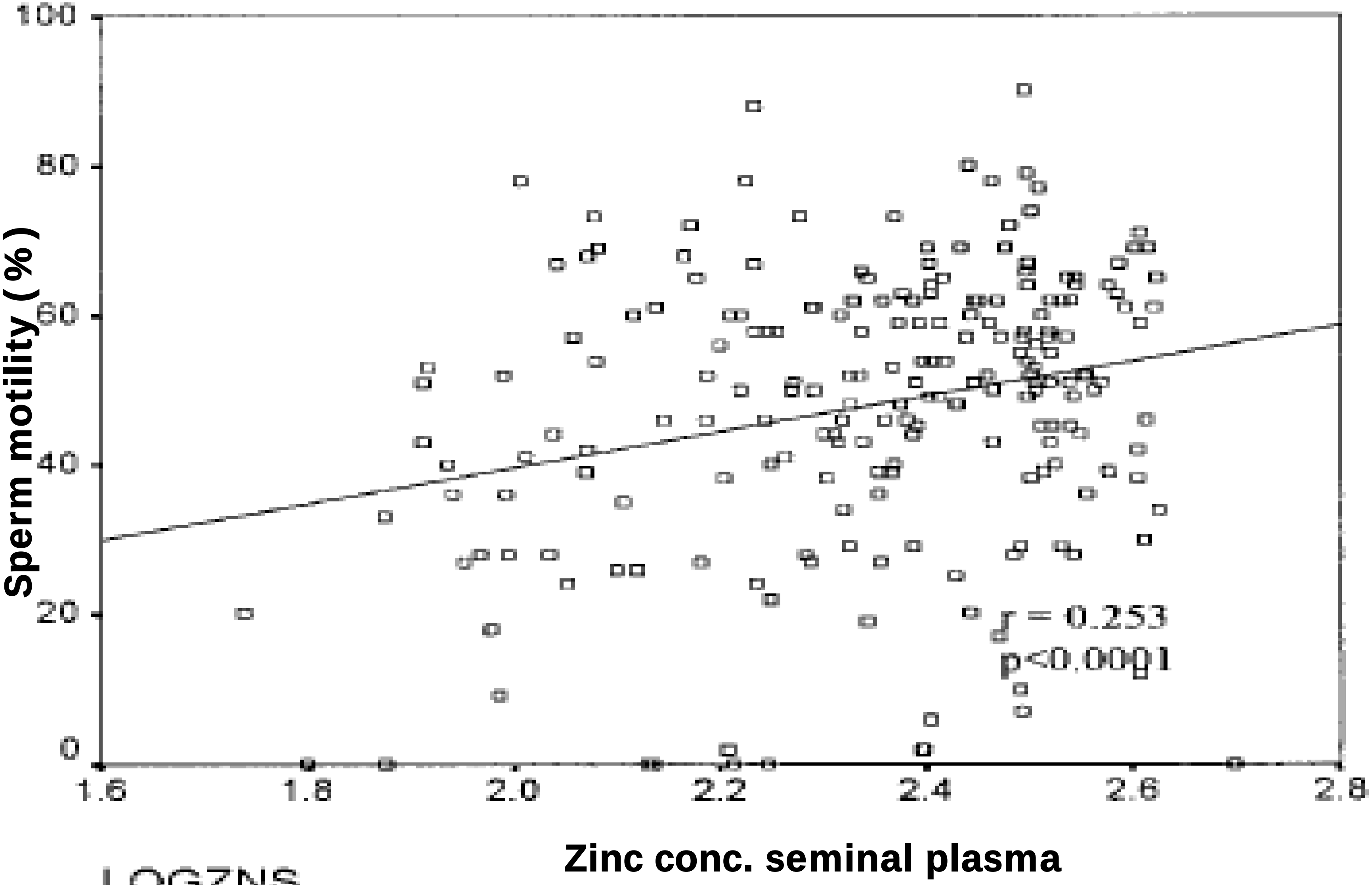
Eskenazi B *et al.* 2005

Male Infertility: Role of zinc



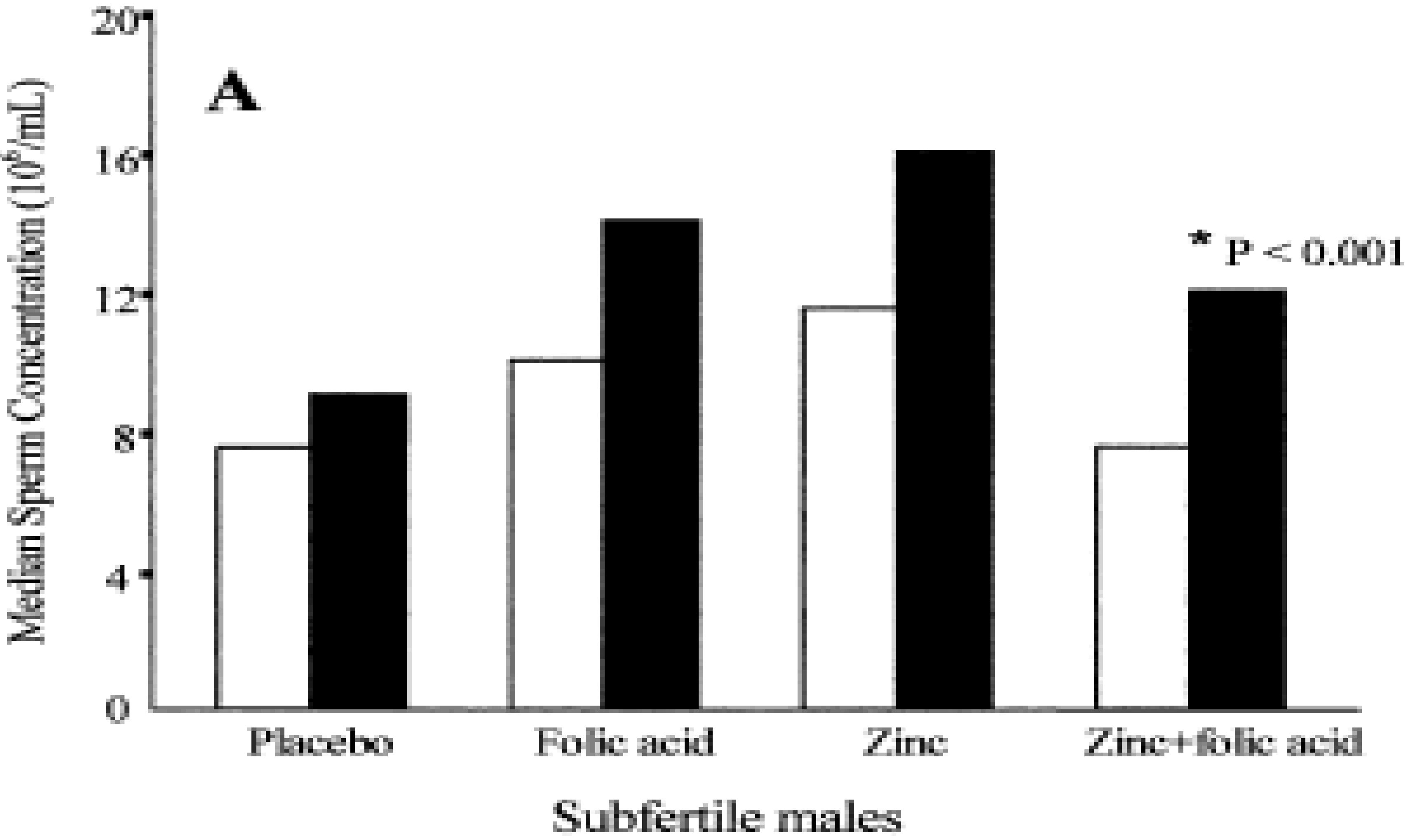
Chia S-E *et al.* 2000

Male Infertility: Role of zinc



Chia S-E *et al.* 2000

Male Infertility: Role of zinc supplements

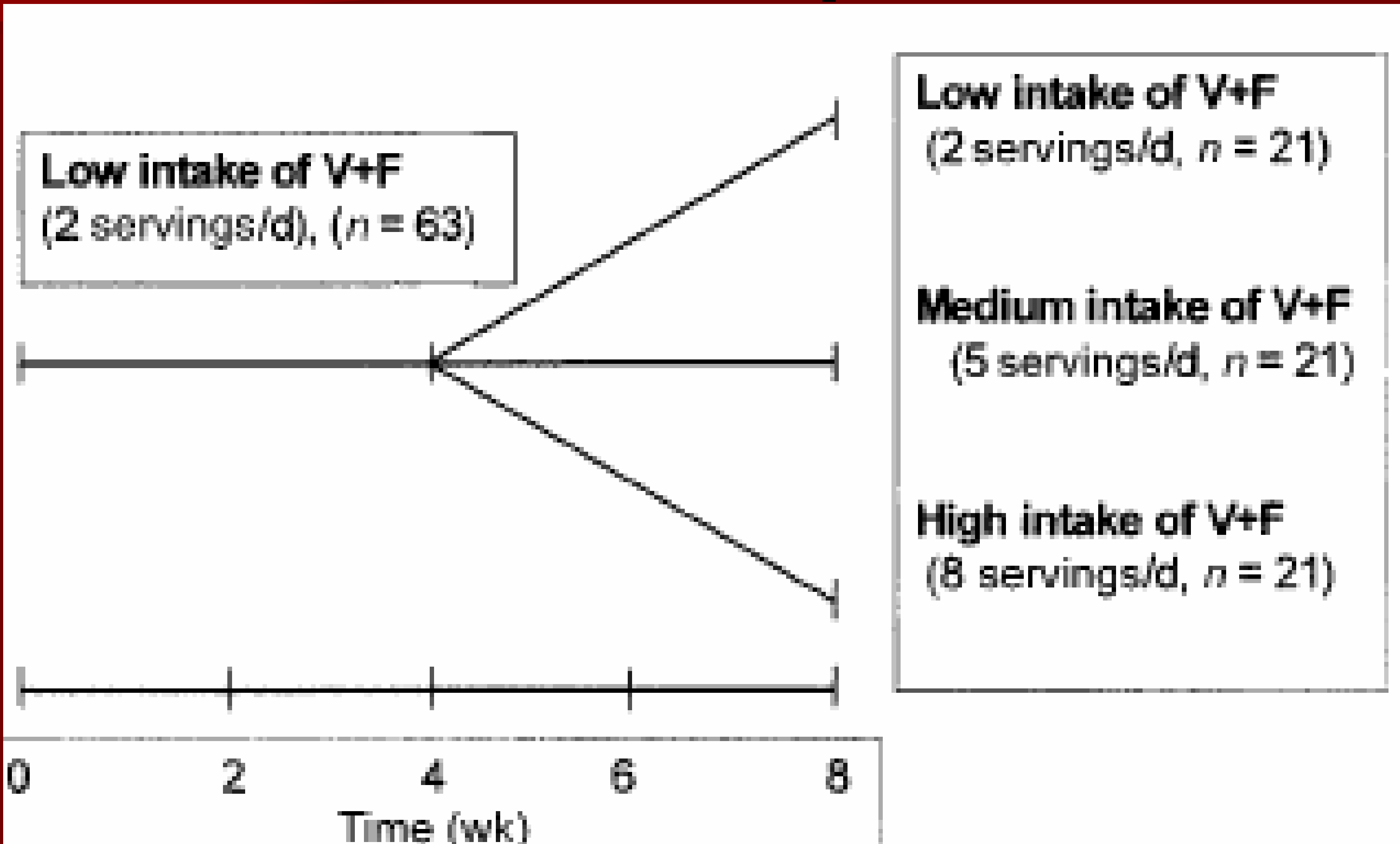


Wng W-Y *et al.* 2000

What is then to be done?

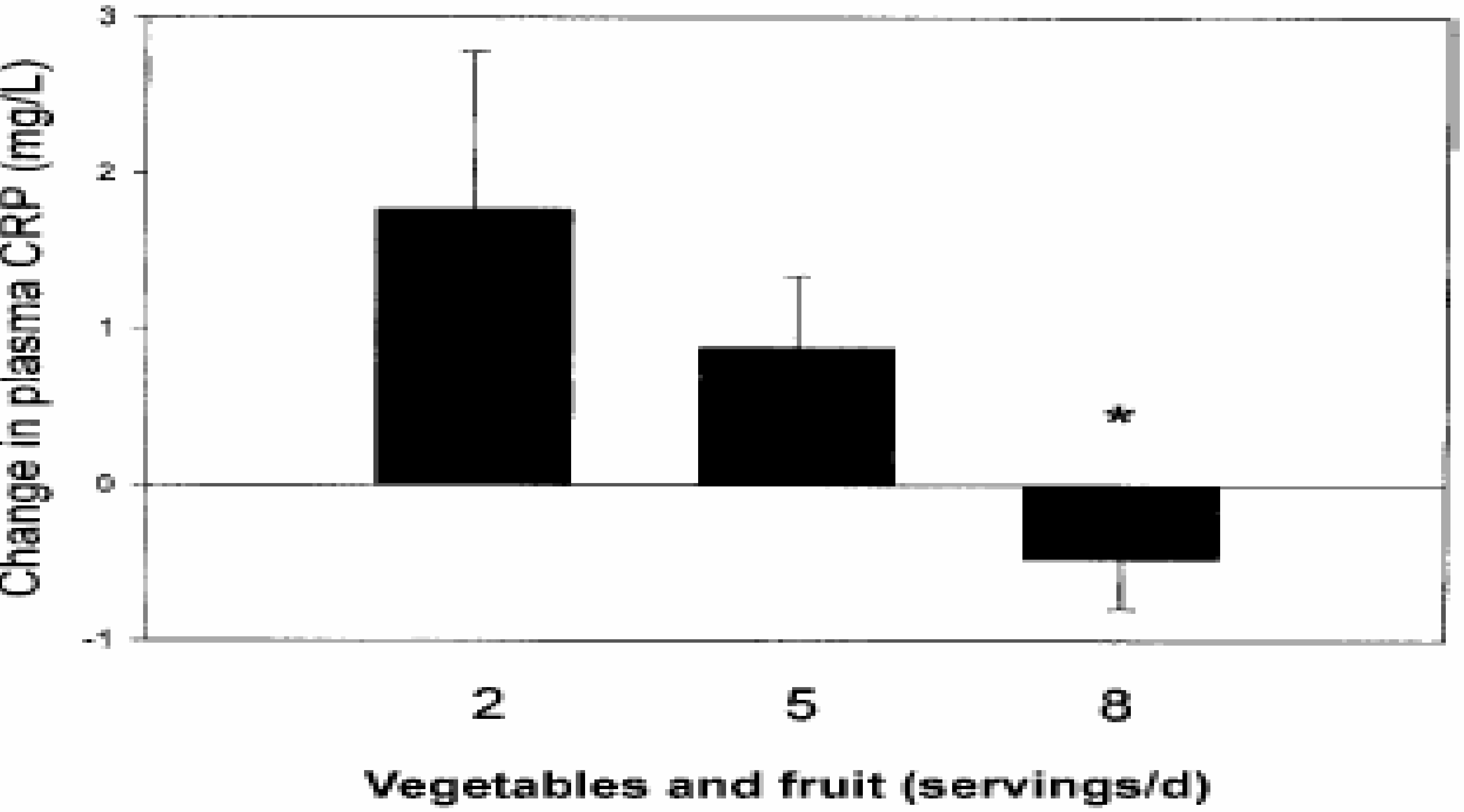
- Control inflammation

CRP change in relation to fruit and vegetable consumption



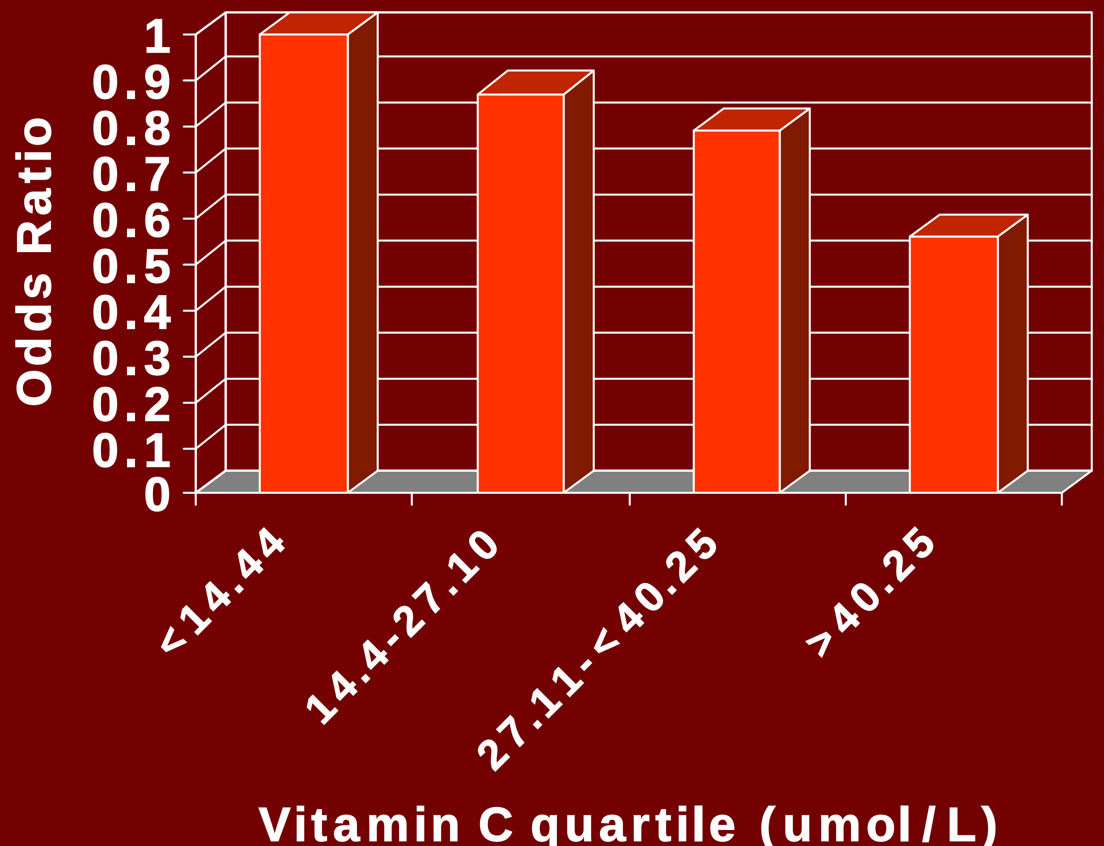
Watzl B et al. 2006

CRP change in relation to fruit and vegetable consumption



Watzl B *et al.* 2005

Vitamin C in relation to CRP

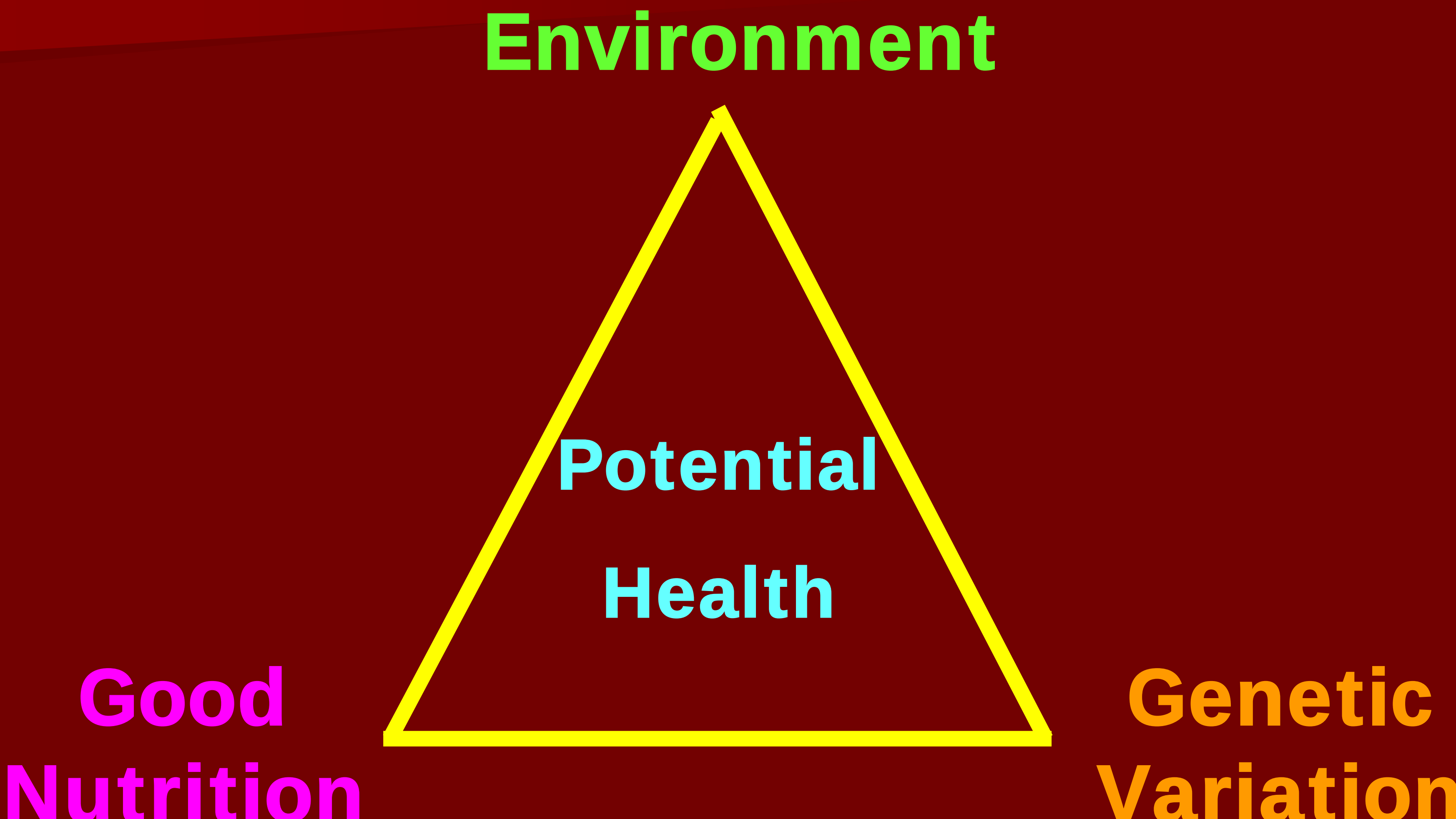


Wannamethe SG *et al*. 2006

What is then to be done?

- Control inflammation
- Eat a variety of foods
- Keep a healthy body weight
- Physical activity
- Supplements?? (side effects)

Conclusion: What of the Future



The Role of Zinc in Child survival

Ngashi Ngongo, MD, MPH.
UNICEF South Africa

Technical Symposium of IZASA
Pretoria, 16 August 2006

Outline of the presentation

1. **Child mortality: Burden and causes**
2. **Zinc supplementation for treatment**
3. **Preventive Zinc supplementation**
   - **Impact on child morbidity**
   - **Impact of Child mortality**
4. **Current UN Position**

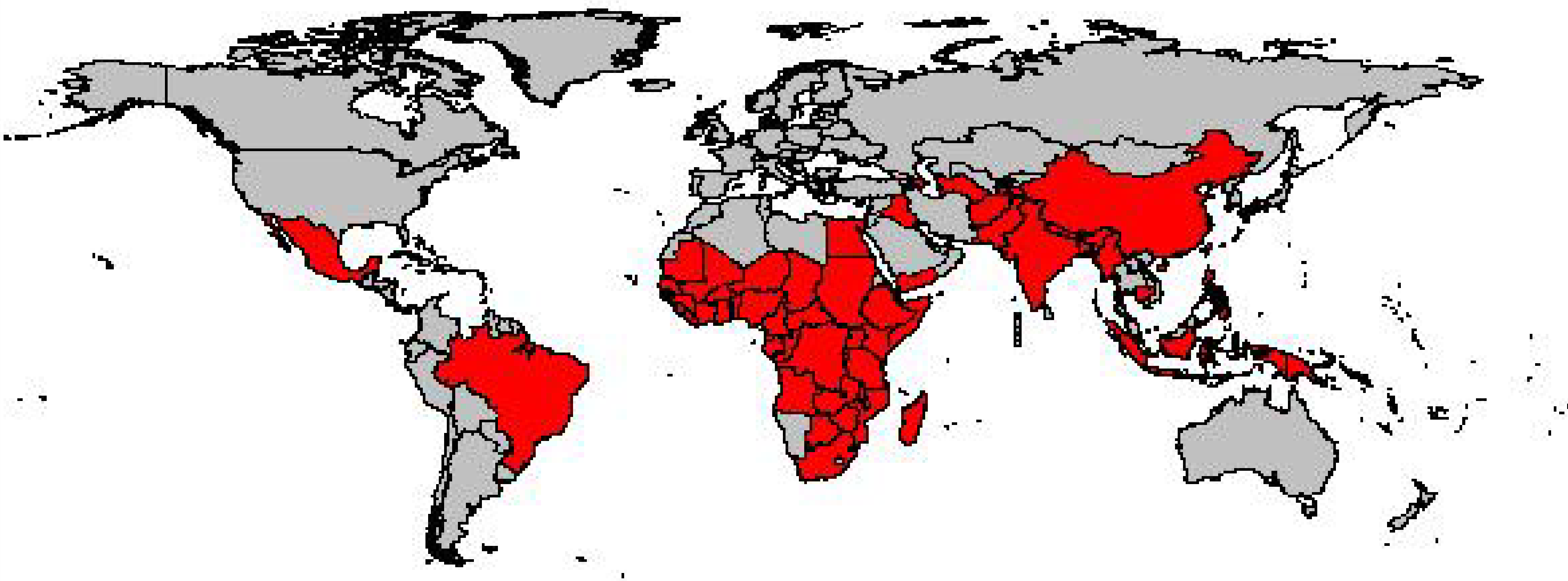
Child Mortality: Burden and Causes

- Every year, 10 million children <5 die, majority of them from preventable and treatable diseases

- Existing cost-effective interventions can save two thirds of children's lives globally each year

- MDG 4 calls for by 66% U5MR by 2015 – Only universal access can achieve this

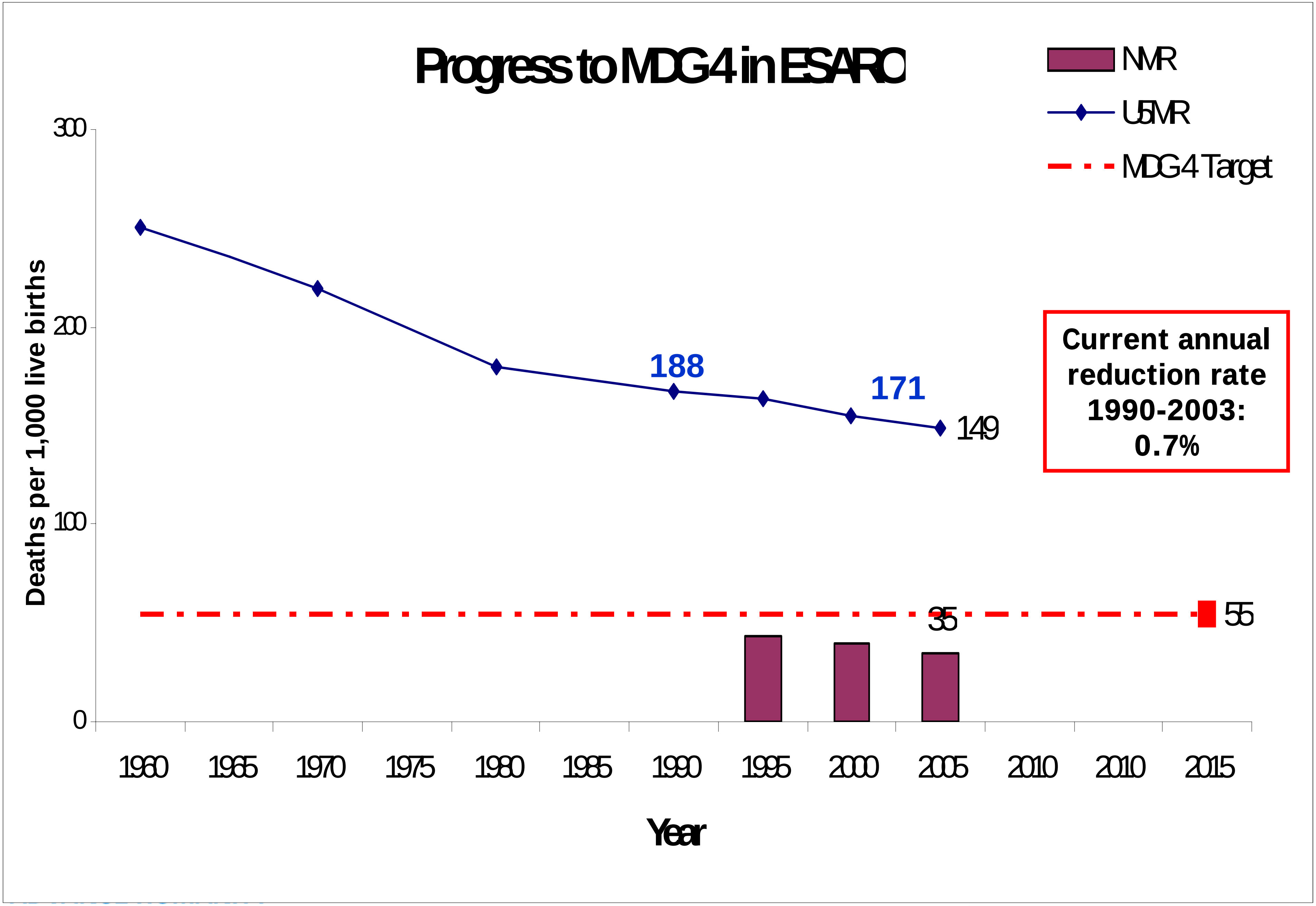
60 Child Survival Countdown Priority countries – 41 in SSA



Criteria:

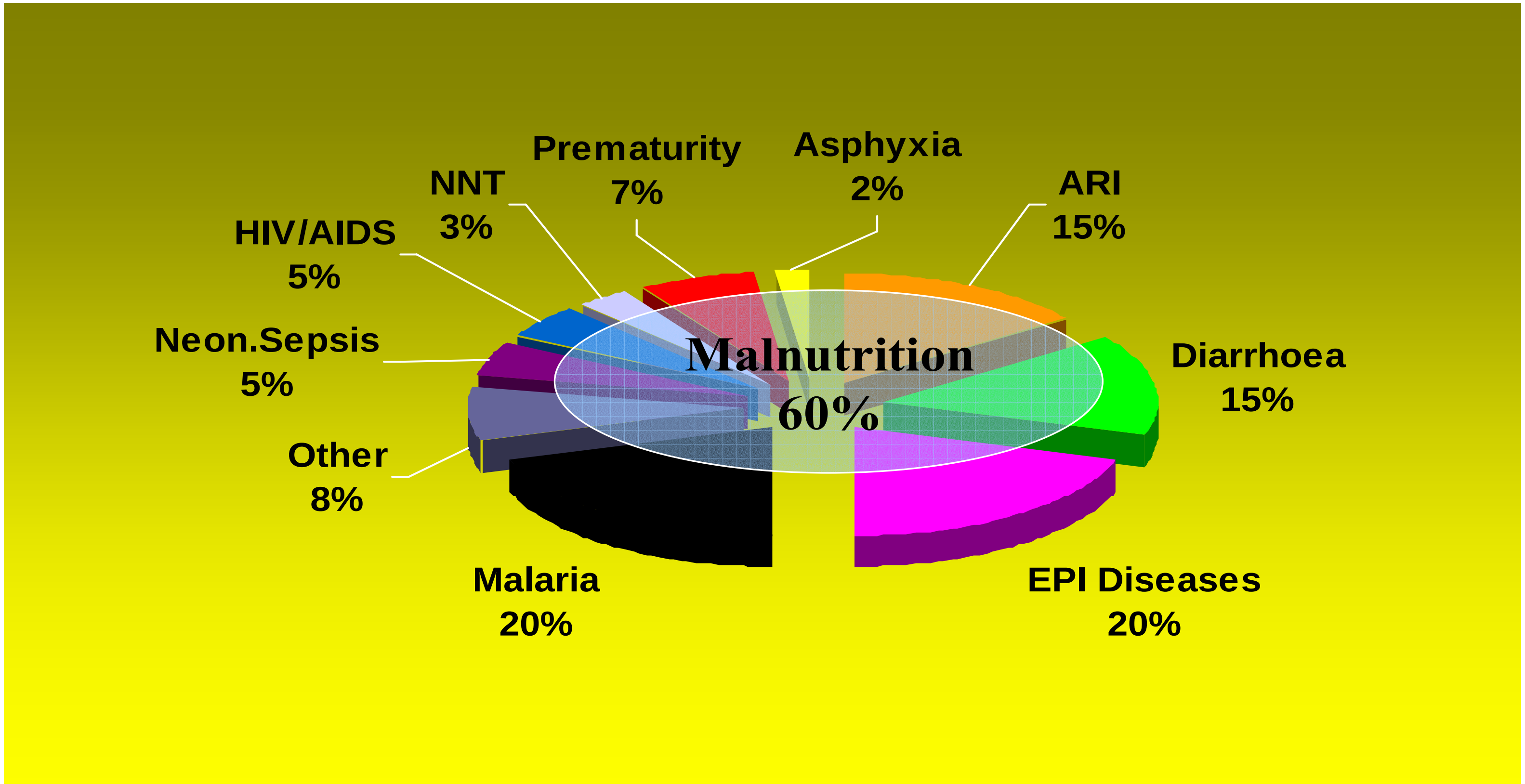
<u>Either</u> **total number of under-five deaths ≥ 50,000**

<u>Or</u> **under-five mortality rate ≥ 90 per thousand**



Progress to MDG4 in ESARO
NMR
U5MR
MDG4 Target
300
200
100
0
Deaths per 1,000 live births
188
171
149
Current annual reduction rate 1990-2003: 0.7%
35
55
1960
1965
1970
1975
1980
1985
1990
1995
2000
2005
2010
2010
2015
Year

Causes of Under Five Mortality in very high U5MR areas in Africa (>150)



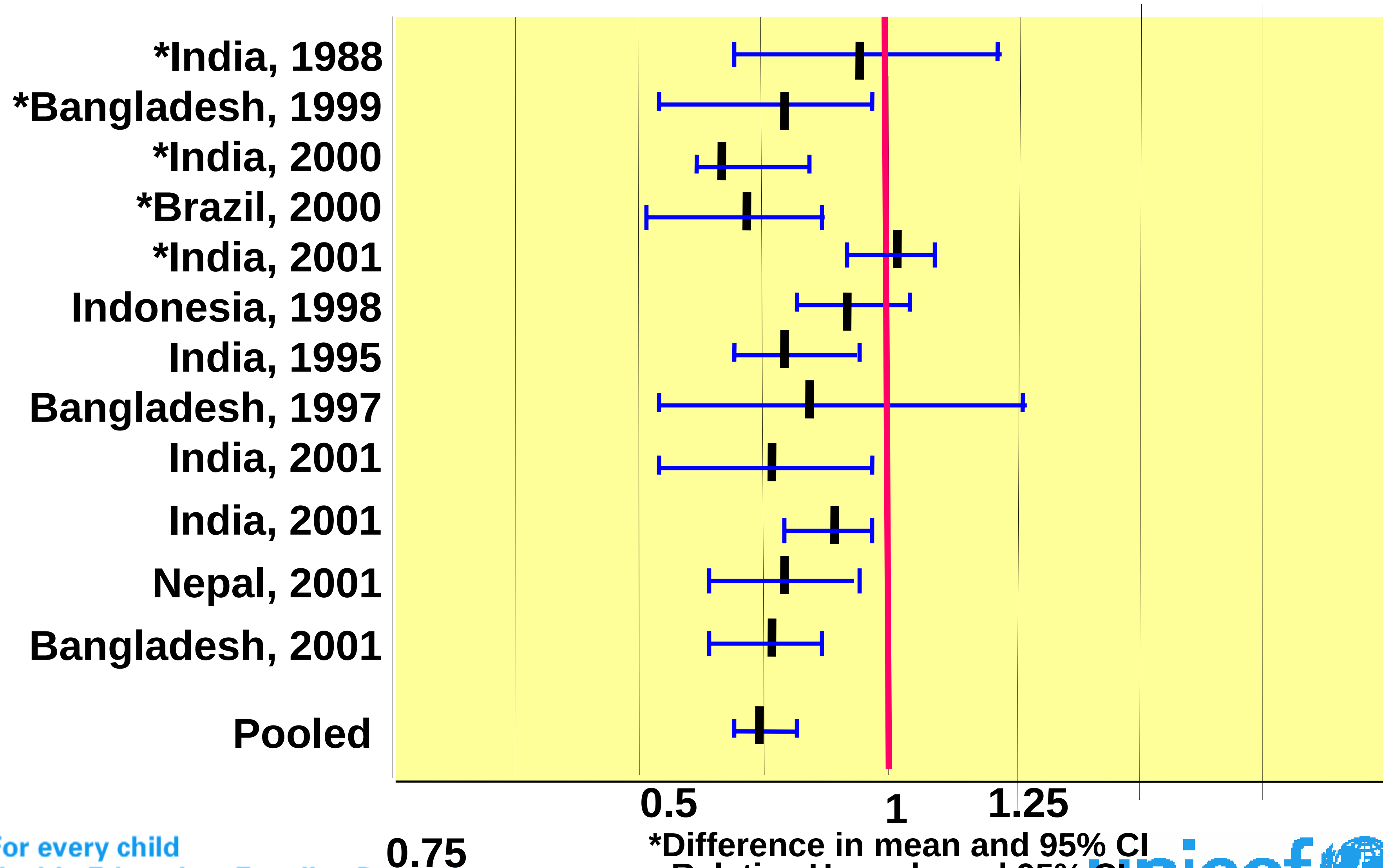
Source: UNICEF 2001

50% of all U5 deaths caused by diarrhea, ARI and malaria

For every child
Health, Education, Equality, Protection
ADVANCE HUMANITY

unicef

Effect of Zinc Supplementation on Duration of Acute Diarrhoea/Time to Recovery



*Difference in mean and 95% CI
Relative Hazards and 95% CI

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ADVANCE HUMANITY

Impact of zinc supplementation as part of treatment of diarrhoea

- Set of studies looking the impact of zinc supplementation during an episode of diarrhoea
  - Reduction of diarrhoea duration
  - Reduction of episodes lasting >7 days
  - Reduction in frequency and volume of stools

- Set of studies looking the impact of continued zinc supplementation after end of episode:
  - Reduction in hospitalization rates
  - Increased ORS prescription and use rates
  - Decreased irrational antibiotic use rates
  - Decreased antidiarrhoeal use rates

Additional Preventive Aspects of Zinc Treatment

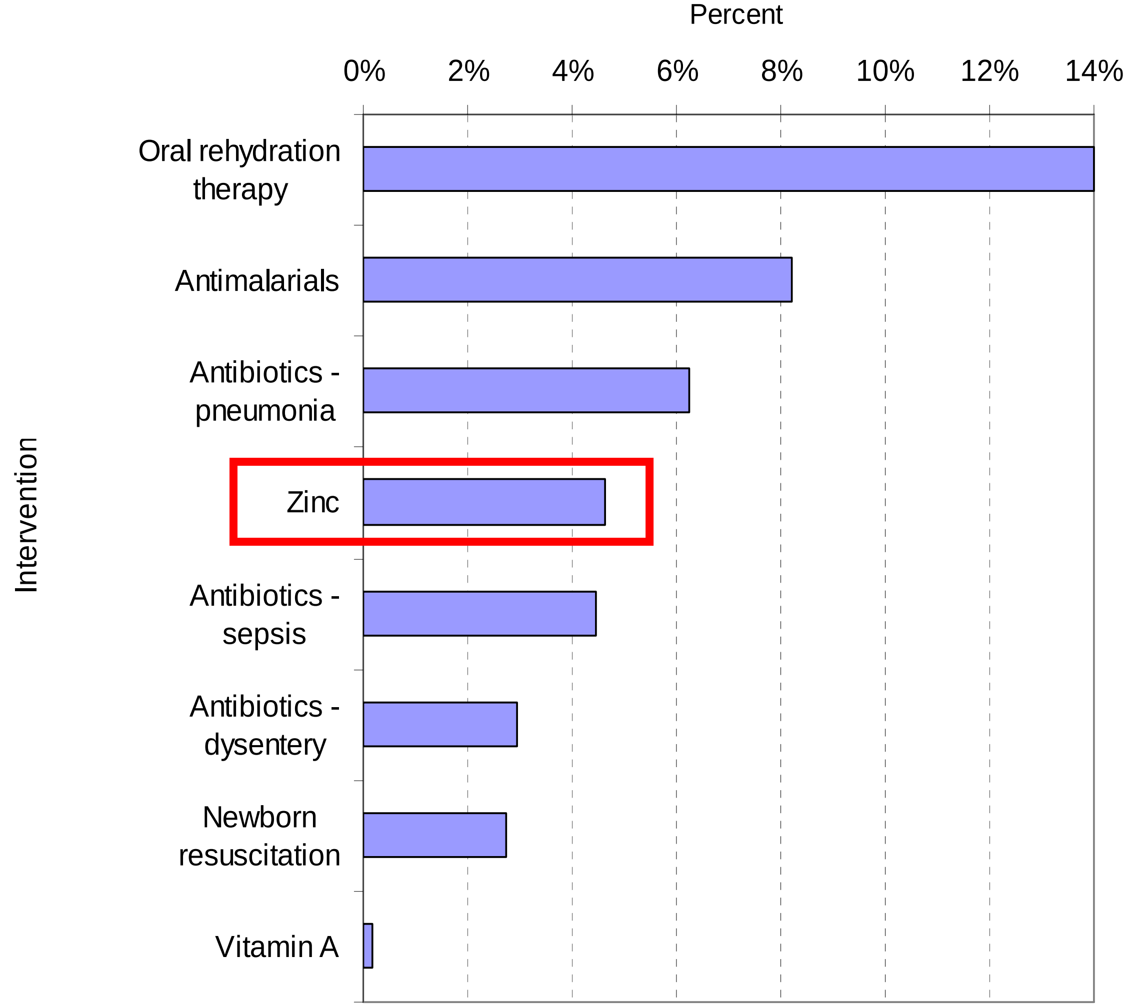
- In a large community-based (effectiveness) trial, zinc supplementation
  - Reduced overall mortality (non-injury) by 60%
  - 23% reduction in diarrhea duration
  - Halved inappropriate antibiotic use
  - Increased ORS use by 50%

  (Baqui, Black, Arifeen. BMJ 2003)

- Zinc supplementation for 10-14 days has preventive effect on childhood illnesses in the 2-3 months after treatment
  - 34% reduction in pneumonia (5 studies)
  - 36% reduction in malaria (2 studies)

Treatment

Percent of total deaths preventable by single treatment interventions in the Eastern and Southern Africa Region*



* Based on 13 countries contributing 95% of under-5 deaths in the Eastern and Southern Africa Region

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Preventive zinc supplementation and child Mortality

- Two large studies conducted in Nepal and Pemba indicate the following:
  - Daily zinc supplementation in children <3yrs of age leads to a modest, non-significant 9% reduction in mortality
  - Reviewing all trials of zinc supplementation and mortality in young children (excluding those on selected populations), the mortality reduction remains 9% but significant

Impact of preventive zinc supplementation on child Mortality among selected populations

- Two studies conducted in Brazil and India among selected populations of LBW and SGA:
  - Pooled RR for reducing mortality of 0.35(CI: 95%, 0.16-0.78)
- Two studies among children with diarrhoea receiving zinc in addition to ORS:
  - RR for reducing mortality of 0.49(CI: 95%, 0.25-0.94)

Impact of Zinc supplementation on morbidity in young children

- 11 studies including children from selected and unselected populations showed:
  - Consistent reduction in incidence of diarrhea and acute lower respiratory track infections

- Two large mortality trials in Nepal and Pemba:
  - No significant impact on diarrhea and ALRI
  - The analysis did not identify severe diarrhea and severe ALRI on which greater impact has been previously reported

Zinc: Safety, costs and benefits

- Safety
  - 8,500 children <5 y supplemented in 17 trials
  - 11,880 child years of observation in one trial
  - Vomiting is the only reported adverse effect

- Cost & benefits
  - Costs about US$0.01 per tablet (i.e. US$ .10-.14 per treatment)
  - Reduces hospitalization
  - Reduces use of unnecessary antibiotics
  - Reduces mortality

Robberstad, Strand, Sommerfelt, and Black. Bull WHO 2004.
Baqui, Black, Arifeen. J Health Pop Nutr (In Press).

UNICEF Position on Zinc

- Zinc supplementation is supported as part of routine management of diarrhoea

  (WHO/UNICEF. Joint statement on the clinical management of acute diarrhea. 2004)

- Evidence based measures and/or operational research needed to support the effective implementation of routine treatment of all diarrhoea episodes with ORS and zinc

  (WHO Workshop to Review the Results of Studies Evaluating the Impact of Zinc Supplementation on Childhood Mortality and severe morbidity. Geneva 2006)

- Although, there is some evidence on the benefit of large scale supplementation, results are conflicting and a meta-analysis of all Zinc supplementation trials is currently on-going to guide policy and programming.

UNICEF Position on Zinc

- Current WHO/UNICEF recommendation is the distribution of blister packs of 10 dispersible tablets of 20 mg Zn for daily use for diarrhoea

- UNICEF provides zinc as part of a multi-micronutrient sprinkles formula, used to improve the micronutrient intake in general of infants and young children. Other micronutrients include iron, vitamin A, vitamin C.

- Zinc is also part of a multi-micronutrient supplement meant for use in emergencies.

- It seems to be more cost effective to provide zinc supplements as part of a multi-micronutrient supplement.

Thank you and God bless

Making zinc available to children in South Africa

Lesley Bamford
Child Health Sub-directorate
National Department of Health

- Diarrhoea is an important cause of mortality and morbidity
- Approximately 1.3 million episodes of diarrhoea in children under five years of age are treated in the public sector per year

Current situation

- Hospitals

  Zinc has been part of a Trace Element Mix used to treat children with severe malnutrition

  Galenical – must be mixed by a pharmacist, unstable solution

- Primary Health Care level or where there is no pharmacist – not available

We need a product that is:

- Available in a stable form – tablets best
- Each tablet should contain 10mg or 20mg elemental zinc (or a solution with 10mg/5ml)
- Can be any zinc salt – sulfate, acetate, gluconate
- Tablets must be dispersible – for use in infants and young children
- Unpleasant metallic taste should be masked
- Packaged as a blister pack (10 -14 days)
- Shelf life of at least two years
- Must meet defined quality standards

Production of Zinc Tablets and Zinc Oral Solutions

Guidelines for Programme Managers and Pharmaceutical Manufacturers

World Health Organization

unicef

USAID
FROM THE AMERICAN PEOPLE

USP DQI
United States Pharmacopeia
Drug Quality and Information Program

JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

World Health Organization

Process

- Guidelines
- Registered with the Medicines Control Council (MCC)
- Procured and distributed

INTEGRATED MANAGEMENT OF CHILDHOOD ILLNESS

SICK CHILD AGE 2 MONTHS UP TO 5 YEARS

South Africa
Department of Health

World Health Organization
Division of Child Health

unicef

SICK YOUNG INFANT AGE 1 WEEK UP TO 2 MONTHS

Diarrhoea page

Does the child have diarrhoea?

IF YES, ASK:	LOOK OR FEEL:
• For how long? • Is there blood in the stool? • How much and what fluid is mother giving?	• Look at the child's general condition. Is the child: Lethargic or unconscious? Restless and irritable? • Look for sunken eyes • Offer the child fluid. Is the child: Not able to drink, or drinking poorly? Drinking eagerly, thirsty? • Pinch the skin of the abdomen. Does it go back: slowly? or very slowly? (more than 2 seconds)

Classify DIARRHOEA

	Signs	Classify	Treatment
for DEHYDRATION in all children with diarrhoea	Two of the following signs: • Lethargic or unconscious • Sunken eyes • Not able to drink or drinking poorly • Skin pinch goes back very slowly	**SEVERE DEHYDRATION** Red	➢ **Start treatment for severe dehydration (Plan C, p. 15)** ➢ **Refer URGENTLY** ➢ **Give frequent sips of ORS on the way** ➢ **Advise the mother to continue breastfeeding when possible**
	Two of the following signs: • Restless, irritable • Sunken eyes • Drinks eagerly, thirsty • Skin pinch goes back slowly	**SOME DEHYDRATION** Yellow	➢ Give fluids to treat for some dehydration (Plan B, p.14) ➢ ~~Advise mother to continue breastfeeding and feeding~~ ➢ Give zinc for 2 weeks (p. 9) ➢ ~~Advise the mother when to return immediately (p. 21)~~
	• Not enough signs to classify as severe or some dehydration	**NO VISIBLE DEHYDRATION** Green	➢ Give fluid and food for diarrhoea at home (Plan A, p. 14) ➢ ~~Advise mother when to return immediately (p. 21)~~ ➢ Give zinc for 2 weeks (p. 9) ➢ Follow up in 5 days
and if diarrhoea 14 days or more	• Dehydration present	**SEVERE PERSISTENT** Red	➢ **Start treatment for dehydration** ➢ **Refer URGENTLY** ➢ **Give frequent sips of ORS on the way** ➢ **Give additional dose of Vitamin A (p.16)**
	• No visible dehydration	**PERSISTENT DIARRHOEA** Yellow	➢ Counsel the mother about feeding (p. 18 – 19) ➢ Give additional dose Vitamin A (p. 16) ➢ Give zinc for 2 weeks (p. 9) ➢ Follow-up in 5 days ➢ Advise the mother when to return immediately (p.21)
and if blood in stool	• Dehydration present or • Age less than 12 months	**SEVERE DYSENTERY** Red	➢ **Refer URGENTLY**
	• Age 12 months or more and • No dehydration	**DYSENTERY** Yellow	➢ Treat for 5 days with ciprofloxacin (p. 8) ➢ Advise when to return immediately (p.21) ➢ Follow-up in 2 days

TEACH THE MOTHER TO GIVE ORAL DRUGS AT HOME

- **Follow the general instructions for every oral drug to be given at home**
- **Also follow the instructions listed with the dosage table of each drug**

Treat for Malaria

- Give the current malaria treatment recommended for your area. See the Malaria Treatment Guidelines.
- If you suspect malaria but cannot test or treat, refer urgently
- Record and notify malaria cases

In all provinces combination therapy must be used. In Kwa Zulu Natal and Limpopo Province use Co-artemether. Elsewhere use provincial guidelines.

Artemether + Lumefantrine (Co-Artemether)

- **Refer URGENTLY if child unable to swallow, or under one year of age**
- **Treat only test-confirmed malaria. Refer if unable to test**
- Watch mother give the first dose of Co-Artemether in the clinic and observe for one hour. If the child vomits within an hour repeat the dose
- Second dose should be taken at home 8 hours later. Then twice daily for two more days
- Give Co-Artemether with food

Weight (age)	CO-ARTEMETHER TABLET	
	Day 1: First dose and repeat this after 8 hours	Days 2 and 3: take dose twice daily
10 – 15 kg (1-5 years)	1 tablet	1 tab twice a day
15 - 25 kg	2 tablets	2 tabs twice a day

Give Zinc Sulphate (or Zinc gluconate or acetate)

- Give all children with diarrhoea zinc for 2 weeks
- Infants less than 6 months give 10 mg elemental Zinc as a daily dose
- Children more than 6 months give 20 mg elemental Zinc as a daily dose

Give Salbutamol for Wheeze

- Give salbutamol with a **spacer** and teach mother how to use it
- If you do not have a spacer, although not ideal, make one with a 500 ml plastic cold drink bottle. Hold the top opening in very hot water to make it soft. Push the Metered Dose Inhaler (MDI) into it. When the bottle cools, the opening will stay the right shape. Then cut off the bottom of the bottle with a sharp knife. Put tape over this cut edge to avoid hurting the child. Place this end over the child's face like a mask. While the child breathes, spray 1 puff into the bottle. Allow the child to breathe for 4 breaths. Repeat this 4-8 times
- You can use a nebuliser to give the first dose (essential for all severe cases, such as for urgent referral) but home treatment should continue with an MDI and spacer

SALBUTAMOL	
MDI — 100 ug per puff:	4 - 8 puffs using a spacer, Allow 4 breaths per puff Repeat 3 to 6 times a day as required
Nebulised salbutamol (2.5 ml nebule) for all severe cases	Dilute 1 ml in 3 ml saline. Nebulise in the clinic If no relief repeat every 20-30 minutes in first hour and 2 - 4 hourly thereafter

Give Prednisone for Recurrent Wheeze and for Stridor

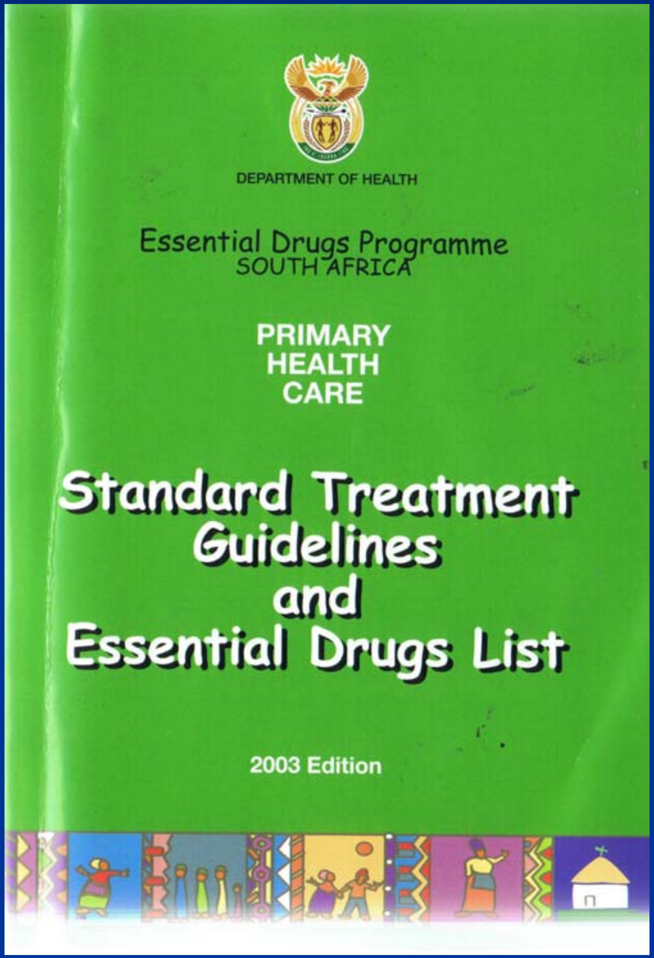
- **Give one dose prednisone as part of pre-referral for stridor**
- Add prednisone treatment to salbutamol if the wheeze is recurrent
- Give prednisone once daily for 7 - 10 days If necessary teach mother to crush the tablets

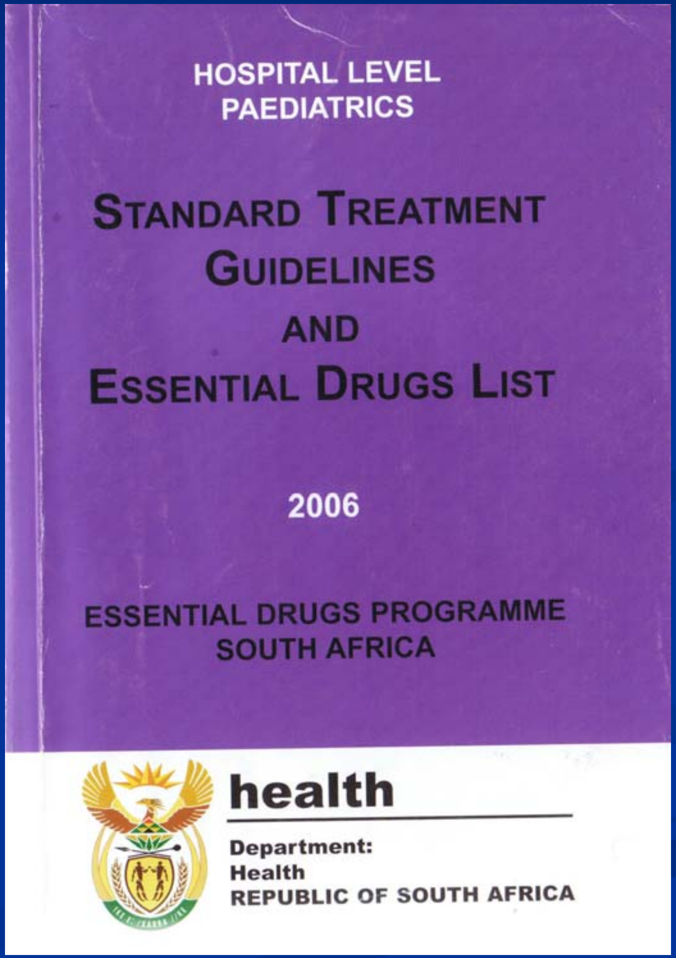
WEIGHT	PREDNISONE 5 mg Once daily for 7 - 10 days for recurrent wheeze and one dose pre-referral for stridor
4 - 6 kg	2 tabs
>6 - 9 kg	3 tabs
>9 - 12 kg	4 tabs
>12 - 14 kg	5 tabs
>14 - 17 kg	6 tabs
>17 - 19 kg	7 tabs
>19 - 20 kg	8 tabs

Give Zinc Sulphate (or Zinc gluconate or acetate)

- Give all children with diarrhoea zinc for 2 weeks
- Infants less than 6 months give 10 mg elemental Zinc as a daily dose
- Children more than 6 months give 20 mg elemental Zinc as a daily dose

Essential Drugs List





Registration with the MCC

- Some confusion regarding food vs medicines
- Multivitamins containing zinc in low doses do not need to be registered
- Certain zinc containing products are currently registered – only one contains only zinc – 50mg
- Manufacturers need to apply to the MCC
- Expedited process – MCC must respond within 9 months
- Fees – Screening fee, application fee, registration fee

Procurement

- Pharmacy Directorate will issue a tender
- Provincial Departments responsible for procurement and distribution

- Thank you

<u>RESUMé : ALAN McKENZIE</u>

MINTEK

Alan McKenzie is currently Manager of the High Temperature Technology Division at Mintek. He has an MSc in Geology and Mineralogy and for the past 15 years has been involved in the field of metallurgy, and applies his skills to the pyrometallurgical field, to assist with process design/ optimisation, problem solving and plant optimisation.

During the second half of 2006 Alan spent a number of months in Europe, assisting the national effort lobbying to minimise the unintended consequences of the European Union REACH legislation, participating in the technical teams preparing guidance documents for use by industry, and ensuring that the negative impacts of the REACH legislation for the Commodities sector are minimised. Alan consults for a number of companies to help them optimise their REACH response programmes.

INTRODUCTION TO EUROPEAN REACH PROGRAMME

Alan McKenzie, Mintek

ABSTRACT

The European Union REACH legislation has been promulgated and came into force on 1 June 2007. All chemical products manufactured in or imported into the EU will have to comply and it is aimed at placing the burden of proof on the manufacturers / suppliers of substances to show that they are safe and not harmful. Non-EU based companies (i.e. exporters into the EU), cannot be forced to comply with REACH (due to WTO rules), but their products must comply with REACH upon transit across the EU border. Whilst REACH is aimed at health and safety within the EU, it has significant market access implications for non-EU producers who export their products into the EU. The rules are simple, no compliance no market.

If non EU companies do not engage in the process, they are at the mercy of their customers in the EU. The customers will have the power to manipulate the market and their suppliers, because the customer holds the REACH registration. Non EU suppliers may not even be able to find alternative customers in the EU because the alternatives may not comply with REACH. Worse still if the current customer in the EU does not register there is no market for the products.

There is much ignorance of REACH; even in the EU the education of the industry is only just starting. Because of this lack of knowledge and understanding many individuals and companies do not know what the potential implications of REACH are for them. There is a great need for training / communication on what REACH will mean for the industry and how best to approach it. This is particularly the case for non EU producers where the requirements and options are materially different from those of EU based companies. Two presentations will be given, the first outlining what REACH is and what needs to be done to comply. The second looks more in depth at the zinc industry, and what companies should start doing to make sure that they are not adversely affected by the legislation.

An introduction to the European Union's REACH legislation

International Zinc Association – Southern Africa.

Technical Symposium 16 August 2007

Alan McKenzie

MINTEK

Overview

- Background
- Principles of REACH
- Health and Environmental Assessments
- Chemical Safety Report / Technical Dossier
- Substances
- Flows of materials – who is responsible
- Authorization
- Timelines

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What is REACH

- REACH is Health and Safety Legislation in the European Union.
- Registration, Evaluation, Authorization and Restriction of Chemicals – EC Regulation No 1907-2006.
- It has no Health and Safety implications outside the EU, but it has marketing implications for non-EU companies.

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Background

- Over more than 30 years Europe has tried to unify regulations.
- In 1994 – Existing Substance Legislation
  - In 1st 5 years 8 substances
  - In 12 years about 60
- REACH proposed in late 1990's to improve the process

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Existing substance regulations

- Studies conducted by member states
- Prioritization was political
- Assurances given that Commodities / Resources were not the target, but in 12 years
  - Pb, Zn, Ni, Cd, Cu, Cr – nearly 10% of total
- Many ‘historic’ substances excluded

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Principles of REACH

- Staggered on scale and severity
  - Registration for all
  - 1t, 10t, 100t and 1000t
  - Authorization if contains >0.1%
    - Carcinogen, Mutagens, Reprotoxin (CMR)
    - Persistent, Bioaccumulative, Toxic (PBT)
    - Defined by Global Harmonized System (GHS)

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Principles of REACH

- Central control – European Chemicals Agency (EChA) with local enforcement
- Assessment of Risk now the responsibility of the Producer (or Importer), burden of proof placed on industry.
- Legislation passed in EU, but guidance to be written by INDUSTRY with some commission oversight
  - In practice the process has been privatized!!

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Basis of REACH

- Health and Environmental Risk assessments to identify all risks.
- Institute controls or Restrictions.
- Evaluation and Authorization to be prioritized on basis of volume and risks.

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Risk assessment process

Existing information
- Public domain
- Company property

Defaults in absence of data

New information
- Bioavailability
- Source apportionment
- Animal testing
- LCA

Minimum basic information

Model

Risk Characterization

Risk reduction

Risk management

This is all REACH requires

The process is the same as under the Existing Substances legislation

Process is iterative

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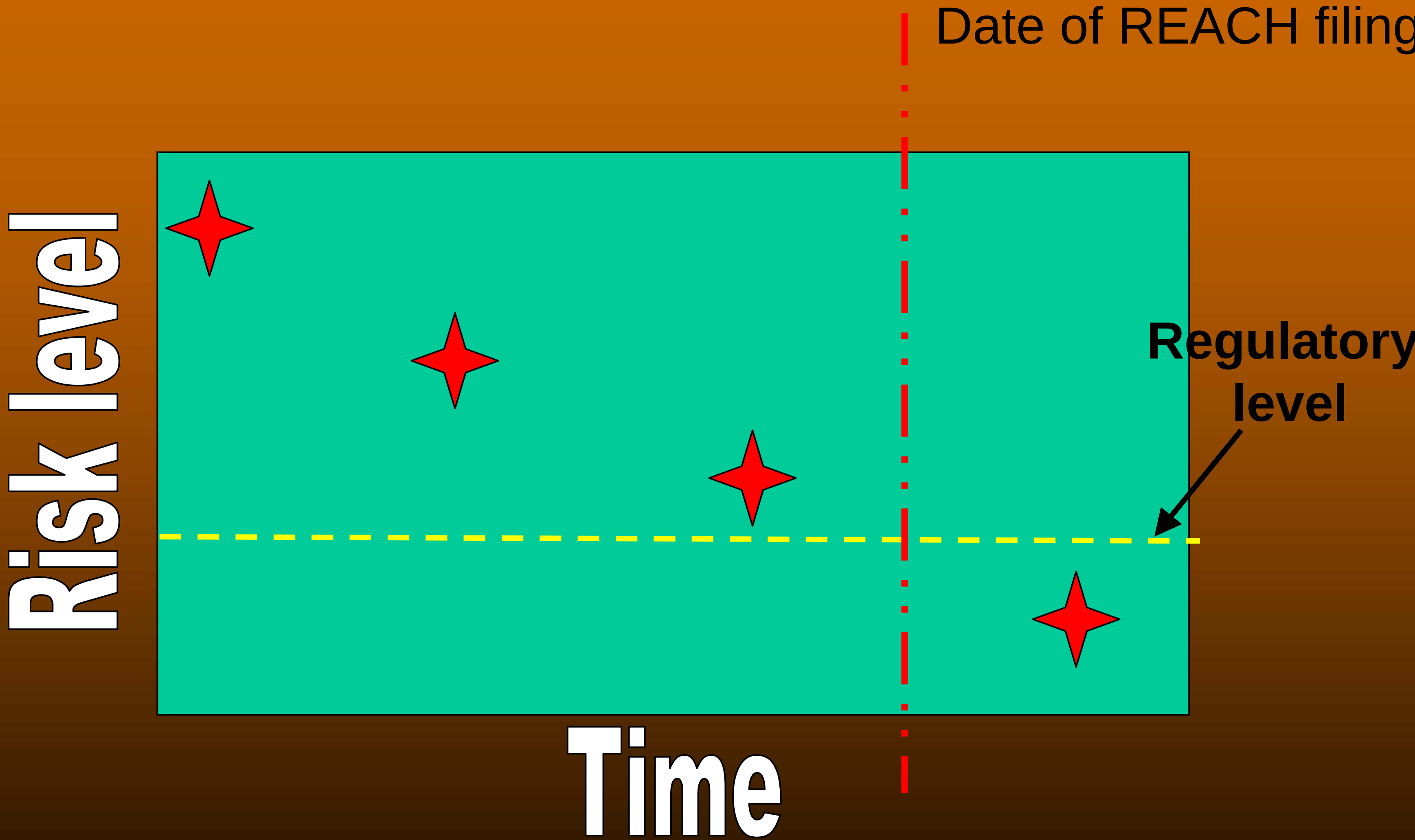
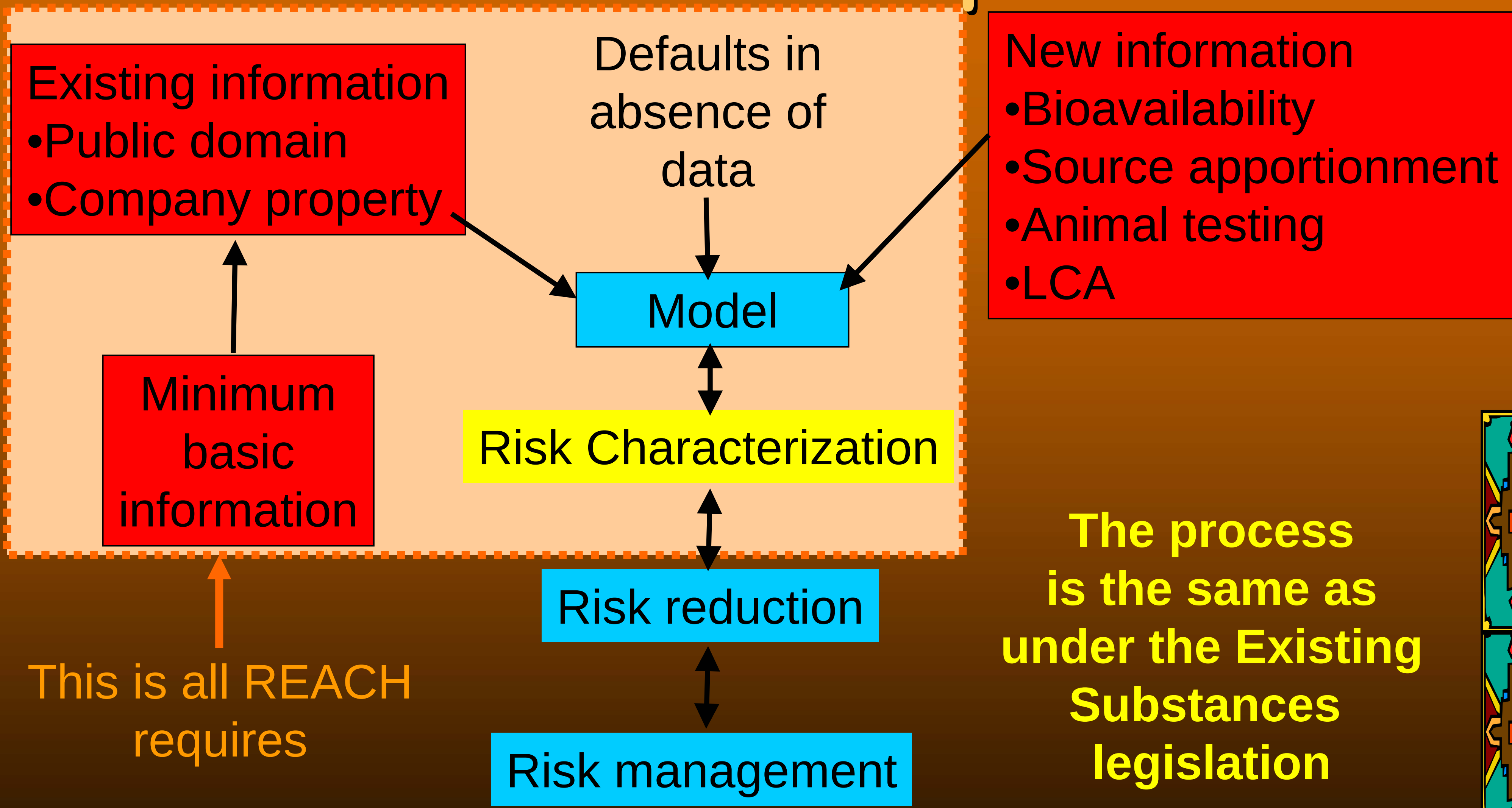
Risk reduction



Risk assessment process



The process is the same as under the Existing Substances legislation

Process is iterative

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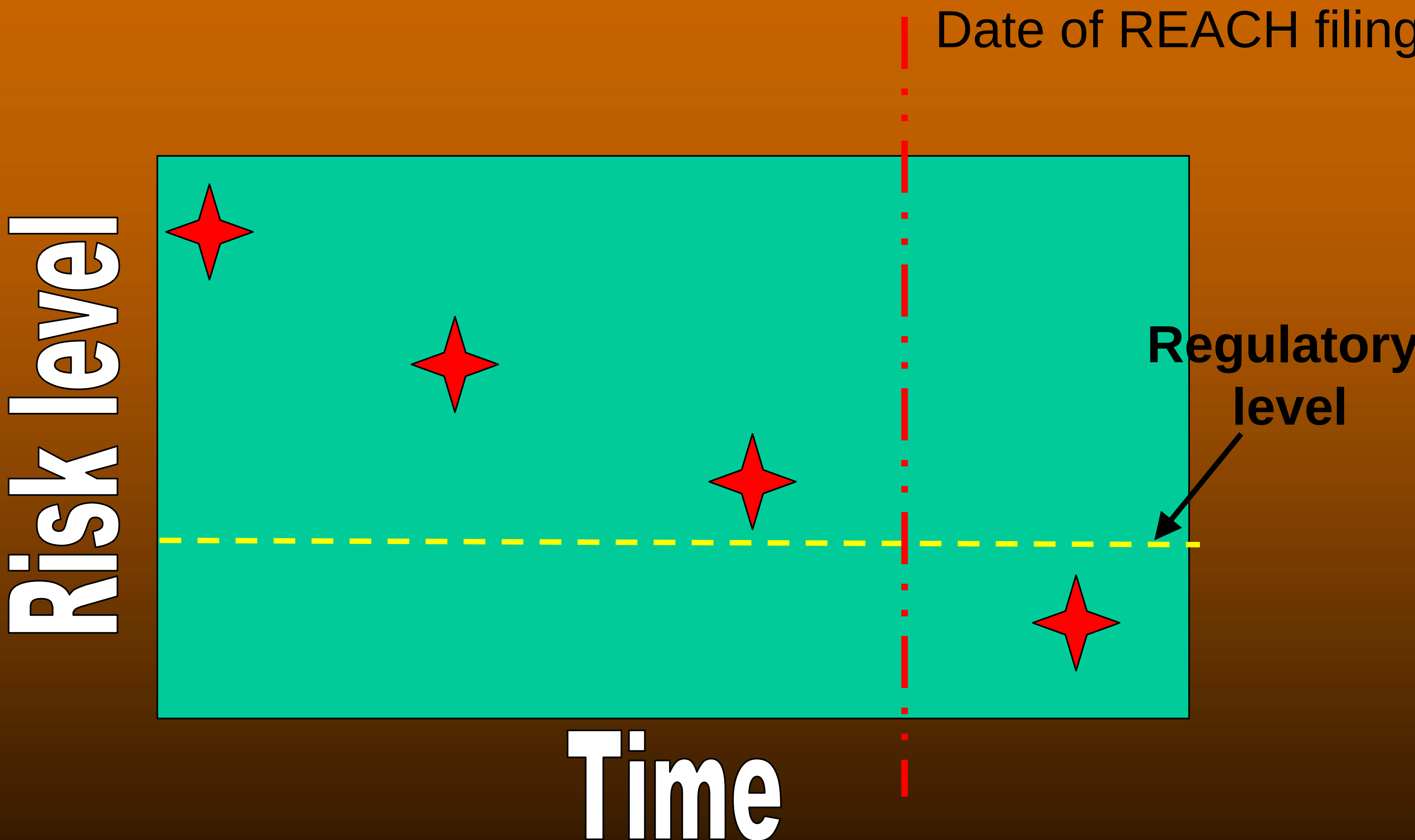
Risk reduction



Risk assessments

- Must be done for all uses
  - E.g. zinc
    - Galvanizing
    - Paint
    - Tires
    - Chemicals
    - Pharmaceuticals
- Must consider all significant forms, or you take all the risk
  - Ni metal, salts, sulfate, nitrate etc
- Local, Regional and Continental level assessment

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Risk Reduction

- The most important tools that have lead to risk reduction for the metals are
  - Source apportionment
    - Minimum of 85% of metal not from metal industry
    - Some in excess of 95%
    - Cd did not do this
  - Bioavailability
    - For Ni raised regulatory level

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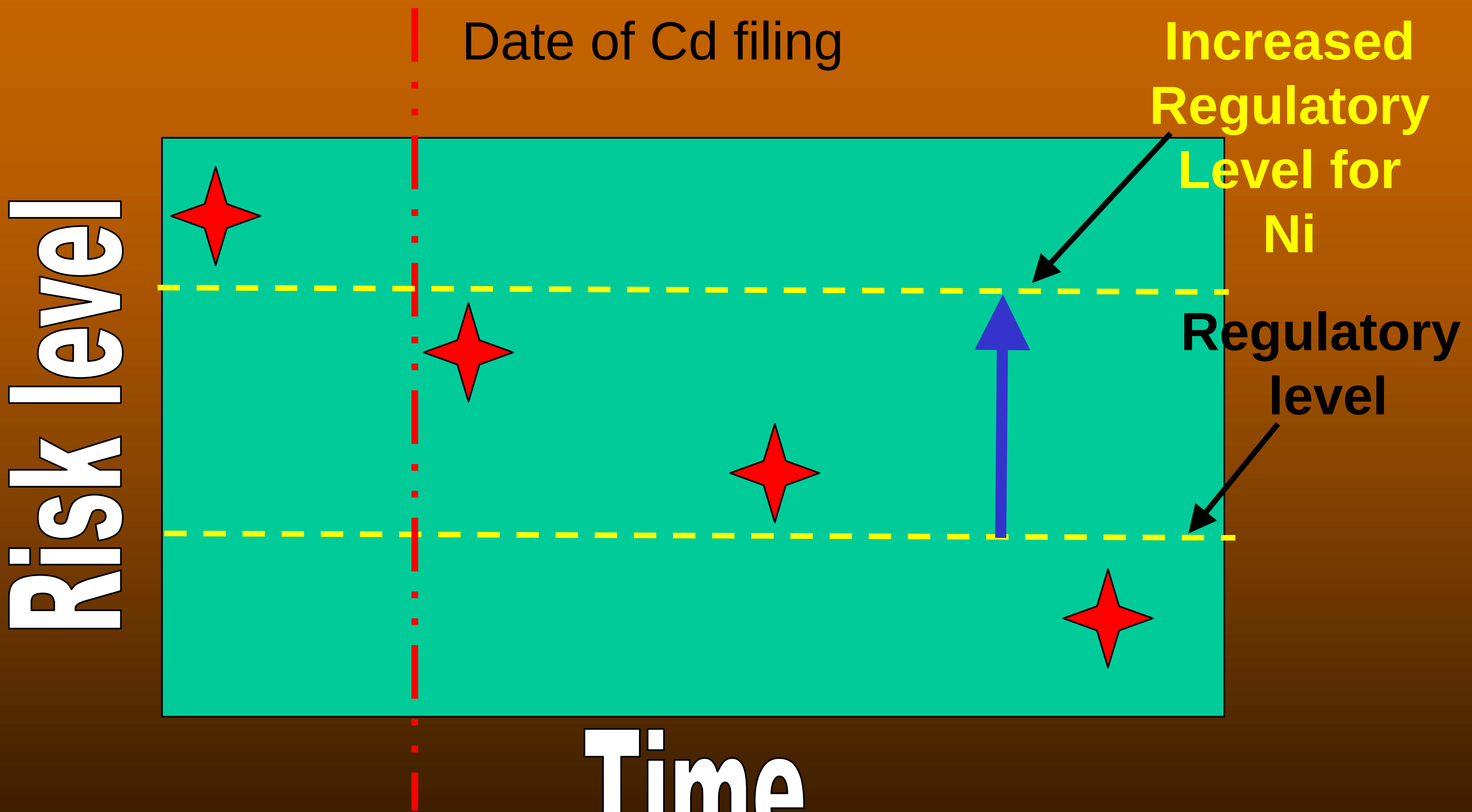
Ni and Cd



Date of Cd filing
Increased Regulatory Level for Ni
Regulatory level
Risk level
Time

Regulations for REACH

- REACH Implementation Projects (RIP's).
- Define how things must be done although not legally binding documents.
- Written by paid consortia on a tender basis – largely industry with some government input.
- Process overseen and monitored by Industry.
- Stakeholder Expert Group (SEG) ultimately approves RIP's.

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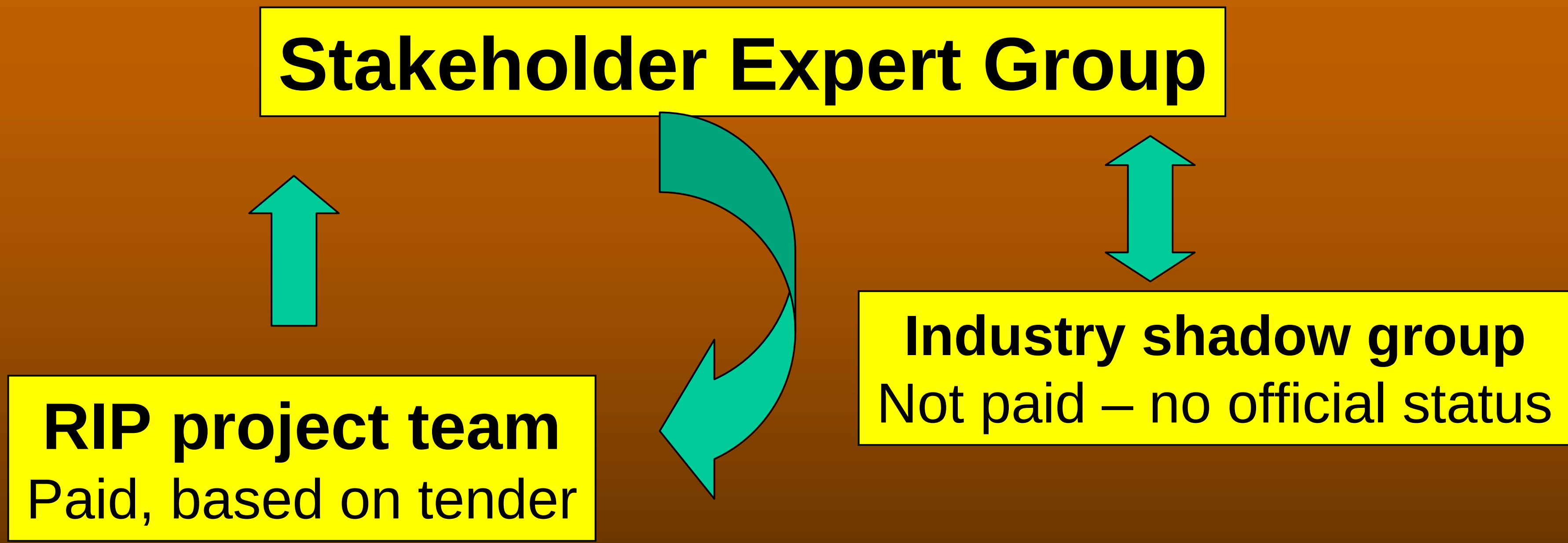
RIP process


Stakeholder Expert Group
RIP project team
Paid, based on tender
Industry shadow group
Not paid – no official status

RIP projects

1. REACH process Description
2. REACH IT
3. RGD for Industry
4. RGD for Authorities
5. Setting up of pre-Agency
6. Setting up of Agency
7. Commission prep for REACH

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Important Projects

- RIP's 3 and 4 are important
  - RIP 3.1 TGD on the Technical Dossier for Registration.
  - RIP 3.2 TGD on the requirements for the CSR – 3 sub-projects.
  - RIP 3.3 TGD on the information for the CSR – 2 sub-projects
  - RIP 3.4 Guidance document on data sharing.
  - RIP 3.5 TGD for downstream users – broken into 2 sub-projects.
  - RIP 3.6 TGD on Classification and Labeling under GHS.
  - RIP 3.7 TGD on the Preparation of an Application for Authorization.
  - RIP 3.8 Guidance on fulfilling requirements for articles.
  - RIP 3.9 Guidance on Socio Economic Analysis – 2 sub-projects.
  - RIP 3.10 Guidance on performing the substance ID check.
  - RIP 4.1 Guidance Document on Dossier Evaluation.
  - RIP 4.2 Guidance Document on Substance Evaluation. – with 4.1
  - RIP 4.3 GD on inclusion of Substances into Annex XIII.
  - RIP 4.4 Guidance Document on preparation of Annex XIV Dossiers.
  - RIP 4.5 Guidance Document on Priority Setting for Evaluation.

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Critical RIP's

- RIP 3.2 containing the technical requirements for producing the CSR including read across of data
- RIP 3.3 the data required for CSR. RIP's 3.2 and 3.3 are very closely aligned
- RIP 3.4 data sharing between parties and consortia
- RIP 3.6 Globally Harmonized System
- RIP 4.3 on the prioritization for Authorization

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Important

- REACH is generic
- It is primarily aimed at the Chemicals industry

BUT

- Must work for
  - Organics
  - Inorganics
  - Commodities / Resources
  - Natural substances
  - Etc

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RIP's

- It is difficult to write RIP's that are generic and at the same time give enough detail to make the process workable.
- RIP's are very powerful as they define how things must be done (although not legally binding).
- Industry can only blame themselves if they get it wrong, they wrote the regulations.
- Very different to how most legislation works, Industry has been given the opportunity to show it is RESPONSIBLE.

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Chemical Safety Report

- Information ultimately compiled into a chemical safety report, includes
  - Health and Environmental Risk assessments
  - Risk reduction and management
  - Information packs for downstream users (material safety data sheets)
- For most chemicals is about 200 to 500 pages
- For metals etc are 3000 to 5000 pages!

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Chemical Safety Report

- The CSR is the basis for Registration
- it is also used for Evaluation
- and Authorization
- Contains;
  - Generic information
  - Plus producer specific information
- Most of the Dossier should be a common filing

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One Substance One Registration

- The authorities want only one CSR per substance
  - Reduce testing
  - Reduce costs
  - More efficiency
- Therefore all associated with the substance should work together
  - Substance Information Exchange Forum
  - Otherwise go it alone

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Substances

- REACH talks about
  - Substances
  - Articles
    - Things made from substances
    - Can have substances in articles
  - Preparations
    - Mixture of substances
- Important for Southern Africa are;
  - Substances
    - Pure Metals etc (not alloys)
    - Intermediates
    - Ores and concentrates
    - Minerals
  - Preparations
    - Alloys

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Substances

Pure Metal — Chemically modified → Used ‘as is’ or transformed

Intermediate — Chemically modified → Totally transformed

Ores and concentrates — No chemical modification → Totally transformed

Mineral — No chemical modification → Used ‘as is’

EU border

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Substances

	Registration and Evaluation	Authorization
Pure Metals etc	Yes	Yes
Intermediates	Yes	No
Ore and Conc	No	Yes
Minerals	No	Yes

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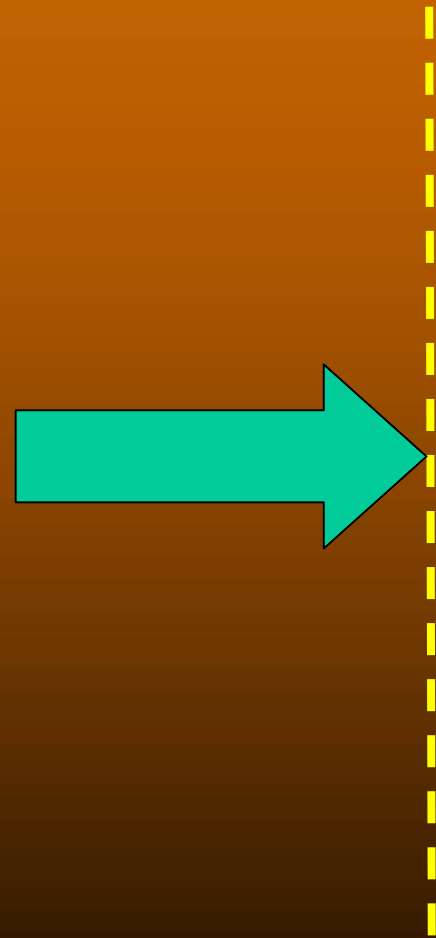
Flow of materials



EU border

The legal entity responsible for signing customs clearance is responsible for REACH filing

Authorization

- Authorization is based on Carcinogen, Mutagen and toxic to Reproduction (CMR) compounds
- Authorization will only be considered
  - If there is adequate control of the substance
  - If there is no alternative material
  - On the basis of socio-economic criteria
- Authorization done on a priority list at the rate of about 30 per year

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Timelines

- 1 June 2007 REACH came into force.
- 18 months for pre-registration – Dec 08
  - All substances, how much of what substance
- + 1000t Register by Dec 2010
  - Produce CSR in 2 years from pre-Reg!
  - Most resources / commodities are +1000t
  - Estimates of 4+ years for CSR
- Authorization ? – based on prioritization

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Globally Harmonized System

- UN initiative for Classification and Labeling.
  - To replace previous systems
  - It is voluntary for countries
  - South Africa aims to implement it in 2008.
  - EU to implement along with REACH.
- Will drive REACH Registration and Authorization requirements.

Problem!

<table>
<tr><th colspan="10">ACUTE ORAL TOXICITY</th></tr>
<tr><td colspan="10">Copper Oxide (LD50= 1291-1340 mg/kg) and Copper Oxychloride (LD50 = 1398-1862 mg/kg) (European Copper Institute, 2005)</td></tr>
<tr><th>ANSI</th><th colspan="3">Highly Toxic</th><th colspan="3">Toxic</th><th>Harmful</th><td colspan="2"></td></tr>
<tr><td>USA</td><td colspan="3">DANGER
May Be Fatal If Swallowed
POISON</td><td colspan="3">WARNING
Harmful if swallowed</td><td>CAUTION
May be harmful if swallowed</td><td colspan="2"></td></tr>
<tr><th>FIFRA</th><th colspan="3">I</th><th colspan="3">II</th><th colspan="2">III</th><th>IV</th></tr>
<tr><td>USA</td><td colspan="3">DANGER
Fatal if swallowed
POISON</td><td colspan="3">No symbol
WARNING
May be fatal if swallowed</td><td colspan="2">No symbol
CAUTION
Harmful if swallowed</td><td>No symbol
CAUTION
No statements</td></tr>
<tr><th>EU/NOHSC/SABS</th><th colspan="2">Very Toxic</th><th colspan="2">Toxic</th><th colspan="3">Harmful</th><td colspan="2"></td></tr>
<tr><td>Europe/Australia/ S. Africa</td><td colspan="2">Very toxic if swallowed (R28)</td><td colspan="2">Toxic if swallowed (R25)</td><td colspan="3">Harmful if swallowed (R22)</td><td colspan="2"></td></tr>
<tr><th>GHS</th><th>Category 1</th><th colspan="2">Category 2</th><th colspan="2">Category 3</th><th colspan="2">Category 4</th><th>Category 5</th><td></td></tr>
<tr><td>Global</td><td>DANGER
Fatal if swallowed</td><td colspan="2">DANGER
Fatal if swallowed</td><td colspan="2">DANGER
Toxic if swallowed</td><td colspan="2">WARNING
Harmful if swallowed</td><td>No symbol
WARNING
May be harmful if swallowed</td><td></td></tr>
<tr><td>LD_{50}</td><td>≤ 5 mg/kg</td><td colspan="2">0-50 mg/kg</td><td>51-200 mg/kg</td><td colspan="2">200-500 mg/kg</td><td>501-2000 mg/kg</td><td>2001-5000 mg/kg</td><td>> 5000 mg/kg</td></tr>
</table>

LD50

Physical Chemical endpoints

Hazard Class	Hazard Category [1]						
Explosives	ble Explosives	Div1.1	Div 1.2	Div 1.3	Div 1.4	Div 1.5	Div 1.6
Flammable Gases	1	2					
Flammable Aerosols	1	2					
Oxidizing Gases	1						
Pressurised Gases							
Compressed Gases	1						
Liquefied Gases	1						
Refrigerated Liquefied Gases	1						
Dissolved Gases	1						
Flammable Liquids	1	2	3	4			
Flammable Solids	1	2					
Self-reactive Substances	Type A	Type B	Type C	Type D	Type E	Type F	Type G
Pyrophoric Liquids	1						
Pyrophoric Solids	1						
Self-heating Substances	1	2					
Water Reactive→Flammable Gases	1	2	3				
Oxidising Liquids	1	2	3				
Oxidising Solids	1	2	3				
Organic Peroxides	Type A	Type B	Type C	Type D	Type E	Type F	Type G
Corrosive to Metals	1						

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Human Health Endpoints

	Health Hazard Classes	Hazard Category [1]				
1	Acute Toxicity, Oral	1	2	3	4	5
1	Acute Toxicity, Dermal	1	2	3	4	5
1	Acute Toxicity, Inhalation	1	2	3	4	5
2	Skin Corrosion/Irritation	1A	1B	1C	2	3
3	Eye Damage/Irritation	1	2A	2B		
4	Respiratory Sensitisation	1				
4	Skin Sensitisation	1				
5	Germ Cell Mutagenicity	1A	1B	2		
6	Carcinogenicity	1A	1B	2		
7	Reproductive Toxicity	1A	1B	2	Lactation	
8	Target Organ ST – Single Dose	1	2	3		
9	Target Organ ST – Repeat Dose	1	2			
10	Aspiration Hazard	1	2			

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Endpoints		GHS Classification and Labeling Systems							
		United Nations GHS October, 2005				European Commission GHS Implementation Proposal August, 2006		Current (Comparable) EU Phrases and Statements	
		Category	**Signal Word**	**Precautionary Statement**	**Pictogram**	**Proposed Category**	**Proposed Statement**	**Current Statement**	**Current R-Phrases**
Acute Toxicity	**Oral**	Cu_2O: 4 CuO: n.c CuM: n.c CuS: n.c	Cu_2O: Warning CuO: n/a CuM: n/a CuS: n/a	Cu_2O: Harmful if swallowed CuO: n/a CuM: n/a CuS: n/a	Cu_2O: 4 CuO: n/a CuM: n/a CuS: n/a	Cu_2O: 4 CuO: n.c CuM: n.c CuS: n.c	Cu_2O: Harmful if swallowed CuO: n/a CuM: n/a CuS: n/a	Cu_2O: Harmful CuO: n.c CuM: n.c CuS: n.c	Cu_2O: (Xn), R22 CuO: n/a CuM: n/a CuS: n/a
	Dermal	All: n.c	All: n/a	All: n.c	All: n/a	All n.c.	All: n/a	All: n.c.	All: n/a
	Inhalation	Cu_2O: 4 CuO§: n.c CuM: n.c CuS: n.c	Cu_2O: Warning CuO: n/a CuM: n/a CuS: n/a	Cu_2O: Harmful if inhaled CuO:n/a CuM: n/a CuS: n/a	Cu_2O: CuO: n/a CuM: n/a CuS: n/a	Cu_2O:4 CuO: n.c. CuM: n.c CuS: n.c	Cu_2O: Harmful if inhaled CuO: n/a CuM: n/a CuS: n/a	Cu_2O: Harmful CuO: n.c CuM: n.c CuS: n.c	Cu_2O: (Xn), R20 (aerosols, particulates) CuO: n/a CuM: n/a CuS: n/a
Skin Corrosion / Irritation		All: n.c	All: n/a	All: n.c	All: n/a	All n.c.	All: n/a	All: n.c.	All: n/a
Serious Eye Damage/ Irritation		Cu_2O§: 2A (or 2B) CuO: n.c	Cu_2O§: Warning CuO: n/a	Cu_2O§: Causes serious eye irritation CuO: n/a	Cu_2O§: CuO: n/a	Cu_2O§: 2A CuO: n.c	Cu_2O§: Causes serious eye irritation CuO: n/a	Cu_2O: Irritating to eyes (proposed) CuO: n.c CuM: Irritating to eyes	Cu_2O; (Xi), R32 (proposed) CuO: n.c CuM: (Xi), R36
		CuM: 2B CuS: 2B	CuM: Warning CuS: Warning	CuM: Causes eye irritation CuS: Causes eye irritation	CuM: No symbol CuS: No symbol	CuM: Not adopted* CuS: Not adopted*	CuM: Causes eye irritation* CuS: Causes eye irritation*		

CURRICULUM VITAE : THAMSANGA JAMES MBEKENI

EDUCATION:

Thamsanga Mbekeni is currently studying for an MBA at the North West University (Potchefstroom Business School).

In 2006, he completed a one-year certificate in Economics and Public Finance at the University of South Africa. He also attended a training course on REACH in Holland the same year.

In 1999, he completed a **BA Administration and Management degree** at the North West University (Potchefstroom) successfully, graduating with the following major courses:

Public Management and Administration
Industrial Psychology

In 1996, he enrolled at the University of South Africa for a B. Admin degree and acquired the following courses:

Business Management ONB 111
Business Management ONB 121

SHORT COURSES:

Course	*Institution*
➢ Government Administration	Japan International Corporation Agency (JAPAN)
➢ Environmental Management (ISO:14001)	University of Potchefstroom
➢ Project Management	Tsheto Educational

ACHIEVEMENTS:

- He served as a member of the North West Economic Development Forum, chaired by the North West Provincial Department of Economic Affairs, from 2003 to 2006.
- In 2005, he was nominated by his employer to be trained by the Department of Trade and Industry on Network Facilitation Skills and DTI incentives.
- In 2003, the Potchefstroom City Council, in conjunction with the National Small Industries Corporation (a Government of India Enterprise), seconded him to India to study the SMMEs of India and the role of the government in developing the sectors with reference to government policies.
- He served in the national task team for the LGWSETA developing unit standards for the training of Local Economic Development Officers in 2002.

WORK EXPERIENCE:

1. **Assistant Director:** ***Department of Trade and Industry, Pretoria. 2006 - present.***

- Project leader for the study on the impact of the European Union's REACH Legislation on South African mineral Export to Europe.
- Involved in the process of drafting the Measurement Bill and the Accreditation Bill for submission to parliament.
  - Developed business cases motivating for creation of National Metrology Institute of South Africa and South African Accreditation System as public entities. Submitting the Business Cases to the National Treasury for approval.

- Development of a strategy that focus on aligning activities of Technical Infrastructure Institutions (SABS, National Metrology Institute of South Africa and South African Accreditation System) to address the priority sectors as identified in the Industrial Policy and ASGISA.
- Motivate for approval of grant funding to SABS, National Metrology Institute of South Africa and South African Accreditation System.
- Evaluate annual reports of SABS, National Metrology Institute of South Africa and South African Accreditation System and submit reports on finances and programs of institution for approval by the Director-General.
- Prepare submissions on appeals from industry regarding compulsory specifications administered by the SABS on products.
- Involved in the disbanding of the South African Quality Institute. The main challenge of the project was the development of the strategy to incorporate the Quality program including personnel to the Small Enterprise Development Agency (SEDA).
- Splitting the National Metrology institute from the CSIR and creating it as a public entity. The process was more or less the same as changing the corporate form of the South African National Accreditation System with more presentations made to the CSIR in this instance.
- Splitting the Regulatory Department of the SABS and establishing it as a public entity independent from the SABS.

Dti position in relation to REACH

TJ Mbekeni

16 August 2007

Background to REACH

REACH: Registration, Evaluation and Authorisation of Chemicals

- **Social:** Improvement and protection of human health
- **Environmental:** environmental protection
- **Economic:** Enhance competitiveness of EU Industrial sector
- **Research:** Enhancing innovative capability of EU chemicals industry

SA Position: we support the above broad objectives but concerned with the unintended consequences

REACH: Implications/Concerns

- Unintended potential negative impact of REACH on mining commodity exports
- 60% of exported ores and minerals would require authorisation
- Registration cost up to €5 million per item
- Negative impact on SMMEs like small scale miners, compliance costs likely to drain little revenue
- Negative impact on poverty reduction strategies and attainment of MDGs

REACH: Implications/Concerns (Cont.)

- Divergence of trade from traditional to new markets
- EU may use REACH as a Technical Barrier to Trade (TBT)
- Lack of technological and human resource capacity to comply
- REACH will be costly to implement
- REACH will impact negatively on down-stream industries/ beneficiation

REACH: Implications/Concerns (Cont.)

- Possible development of substitution material
- Loss of revenue
- REACH could become a global standard
- Potentially high costs of compliance
- Negative impact on poverty reduction strategies and attainment of MDGs

South African Stakeholders:

a) The dti

- Act as a catalyst for the transformation and development of the economy and respond to the challenges and opportunities of the economic citizens, in order to support the government's economic goals of growth.
- Respond to the challenges and opportunities in the economy and society.
- Provide a predictable, competitive, equitable and socially responsible environment for investment, enterprise and trade.

b) **DME**

- Position the minerals and energy sectors for global competitiveness;
- Govern the sectors to be secure, safe, healthy and environmentally sound

c) **SABS**

- GHS

d) **Chemical Industry and Mineral Industry**

Dti intervention

- A bilateral agreement exists between Mintek and the dti, which among other things stipulates that both Mintek and the dti may recommend projects to the Bilateral Committee.

- A project was approved at **the dti**/Mintek bilateral to undertake a study investigating the trade and economic impacts of REACH on South Africa's minerals sector and also to formulate a response strategy.

Scope of the Study

To compile a comprehensive database of South Africa's mineral exports to the EU disaggregated according to commodity, volume, value and destination:

- Compile a database of mineral export data disaggregated according to commodity, volume, value, destination and total South African production.
- Identify high volume or high value mineral commodities exported to the EU.

Scope of the Study (Cont.)

To undertake a quantitative study on the impact of REACH on the minerals sector and the overall South African economy:

- Analyse the macro-economic impact of REACH on the South African economy.

- Analysed the sectoral impact of REACH on the South African economy.

Scope of the Study, (Cont.)

To undertake international visits to other EU trade partners to develop South Africa's response strategy and to the EU to understand the process for complying with REACH

- Identify key trade competitors in the EU minerals export market.
- Direct interaction with trade competitors to present and discuss REACH cooperation.
- Identify key EU industry bodies and REACH authorities.

Scope of the Study, (Cont.)

To understand the processes required for complying with REACH and undertake quantitative analysis of the total direct costs for compliance

- Identify all the steps required for complying with REACH including the development of Chemical Safety Reports (CSRs), undertaking risk assessment studies and compiling technical dossiers.
- Quantify the cost of each step in the REACH process in terms of risk assessment studies, toxicology analysis, man-hours, purchase of specialist reports, and documentation preparation per commodity.

Scope of the Study, (Cont.)

Economic risk assessments per mineral commodity exported into the EU including an investigation into substitution of minerals exported to the EU

- Identify variables to be analysed in order to undertake economic risk assessments assess the macro-economic impact of REACH on the South African economy.
- Identify methodology to be used for economic risk assessments.

Scope of the Study, (Cont.)

A response strategy for South Africa based on the trade and economic aspects of REACH

- Use the information and the results obtained in objectives 1-6 to identify the direct and indirect economic impacts of REACH on the overall economy and the minerals sector.
- To develop options for mitigating and/or managing negative impacts.
- To develop a plan for responding to the impacts highlighted together with timeframe and resources required.

Scope of the Study, (Cont.)

Assess the capacity of SA laboratories to carry out testing in line with REACH requirements on the mineral and chemical sectors

- Assess infrastructure and technology available for testing
- Assess human capacity available for testing
- Estimate financial implications for upgrading testing facilities if needed

Questions and Comments.

Implications of REACH for the Zinc industry

International Zinc Association – Southern Africa.

Technical Symposium 16 August 2007

Alan McKenzie

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Overview

- Do you have to comply?
- What should you do?
- Understand your products.
- Classification and Labeling.
- Commodity Associations.

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Fact

- As of 1 Dec 2008, all substances or preparations, produced or imported into the EU will have to comply with REACH.
- Simple philosophy, **No Compliance – No Market.**

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Timelines

- 1 Dec 2008 – Pre-registration for all
- 1 Dec 2010 – Registration
  - + 1000tpa
  - All CMR containing materials
- 1 Dec 2013
  - + 100 tpa
- 1 Dec 2018
  - + 1 tpa
- No Pre-registration means immediate Registration (above timelines do not apply)

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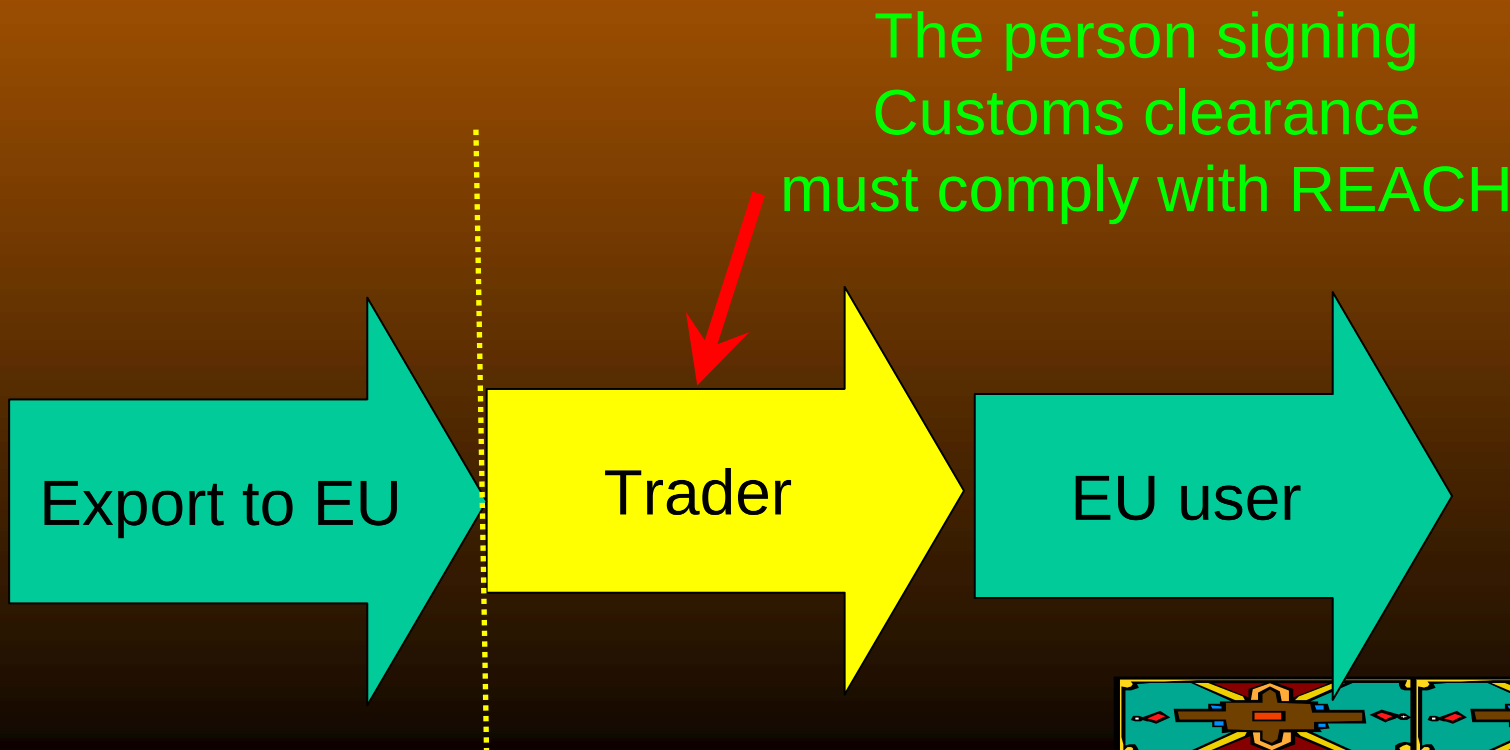
Implementation

- EU can not place any requirements on non-EU companies (WTO rules). Therefore legally non EU entities don't have to do anything.
- However, 'off the record' the EU would like all to come to the party.



What must I do

- There are a number of very good reasons to engage in the process.
  - Control, or at the mercy of your customer
  - Market access
  - Material Stewardship principles
- There are costs associated with participation, this may ultimately drive what you decide to do.

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What must companies do?

- What do you supply into the EU?
- Understand your product flow.
  - Sell straight to manufacturing / processing company in EU. - Simple scenario.
  - Sell to trader, don’t know the ultimate user. – Complex scenario.
- Assess the implications for you.

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Companies opting out

- It is very likely that some companies that want to be involved will opt out due to the costs.
  - Registration up to R 250 000
  - Mandatory testing per substance R 1 000 000
  - Dossier preparation R 250 000 +
  - Additional testing R 0 to R 30 000 000 per substance.
  - Cost of maintaining legal competences ?
  - Cost of 'only representative' ?

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Do you want Control

- There is an option in REACH for a non-EU party to appoint an 'Only Representative'.
- This allows you to comply directly with all the requirements of REACH and maintain control.
- If you don't you are at the mercy of your customers.

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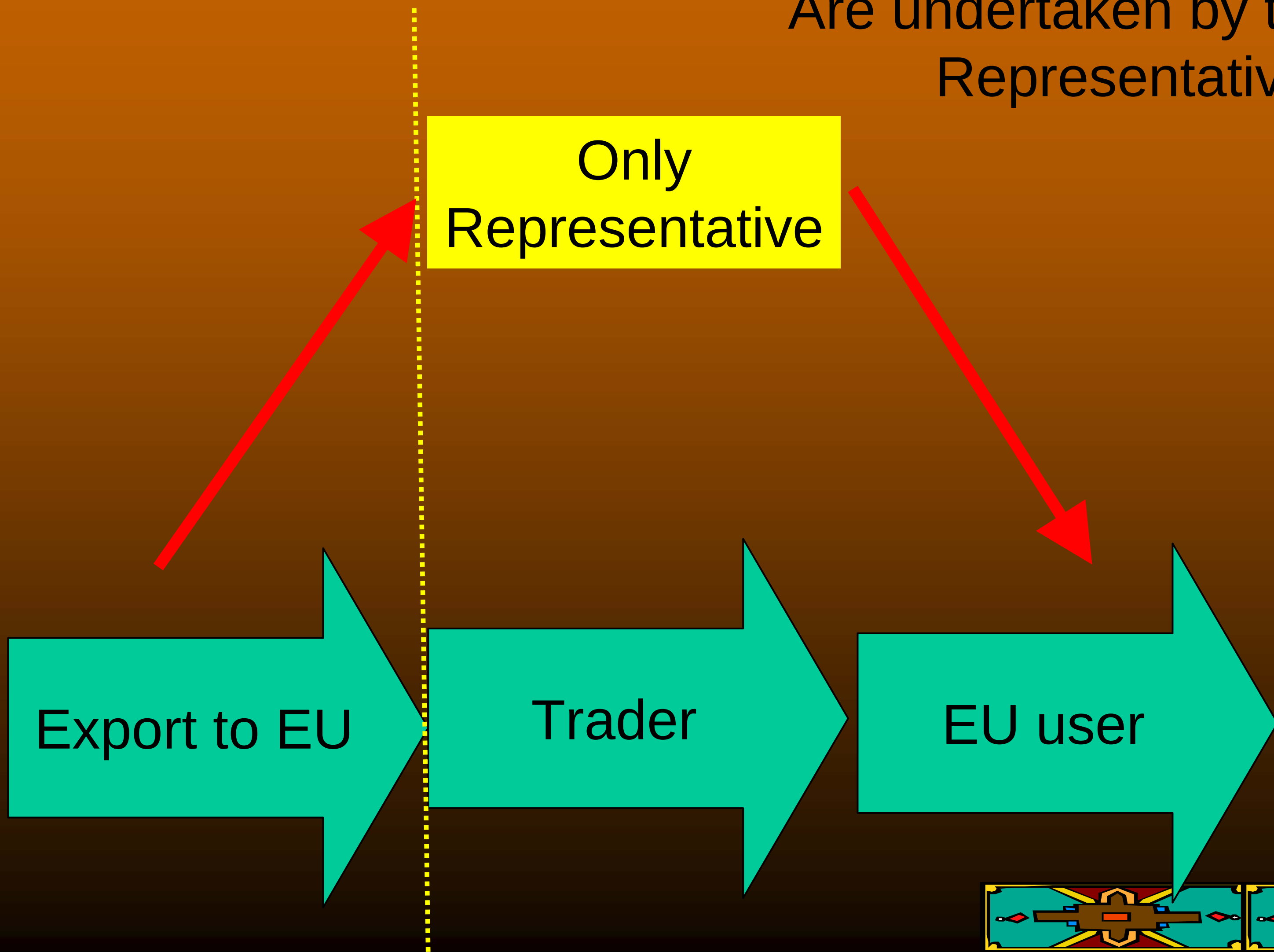
Process flow

All legal requirements for Reach
Are undertaken by the only
Representative



Process

Pre registration

By Dec 2008

Suppliers of the same substance
Given each others contact details
(Substance information
exchange forum - SIEF)

Can work together to
share costs and work
load. Some data has
to be shared.

**If your original classification
For pre-registration is
Incorrect the process will
Not work**

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Product flow

- It is very important that you identify all substances exported into the EU.
- Find out what happens to them.

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Substance identification

- Substance identification is a critical aspect of REACH.
- Will be done via UN Globally Harmonized System (GHS).
- Also to be implemented in SA in 2008.
- Need new MSDS.
- Must be done properly.

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Example

- If you list elements all downstream requirements based on elements.
- The material shipped does not contain these substances (oxides).
- Identification and classification must be done on minerals.
- E.g. Mixture of chromium spinel and mixed silicates.

SiO_2	27.82	8.70
Al_2O_3	4.92	9.82
Fe_2O_3	5.30	4.61
FeO	6.67	10.79
MgO	23.59	14.32
CaO	0.30	0.23
TiO_2	0.13	0.25
Cr_2O_3	19.97	47.60
MnO	0.15	0.22
ZnO	0.05	0.12
NiO	0.58	0.29
V_2O_5	0.06	0.14
CoO	0.019	0.018

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Substances

- REACH works on substances.
- The toxicity is related to the substances.
- For classification 'easier' to use bulk chemical composition. But significant downstream implications.
- If elements are used may be subject to registration etc for each element.

CMR substances

Substance	Classification	Substance	Classification
Beryllium	Carc Cat 2	Nickel dioxide	Carc Cat 1
Beryllium Oxide	Carc Cat 2	Dinickel trioxide	Carc Cat 1
Be compounds, except Al-Be silicates	Carc Cat 2	Nickel sulphide	Carc Cat 1
Asbestos	Carc Cat 1	Nikel subsulphide	Carc Cat 1
Refractory ceramic fibres	Carc Cat 2	Diarsenic trioxide	Carc Cat 1
Chromium (VI) trioxide	Carc Cat 1 Muta Cat 2	Diarsenic pentoxide	Carc Cat 1
Dichromate compounds	Carc Cat 2 Muta Cat 2 Repr Cat 2 or 3	Arsenic acid and salts	Carc Cat 1
Chromate compounds	Carc Cat 1 or 2	Cadmium chloride	Carc Cat 2 Muta Cat 2 Repr Cat 2
Chromium (VI) compounds	Carc Cat 2	Cadmium sulphate	Catc Cat 2 Muta Cat 2 Repr Cat 2
Cobalt dichloride	Carc Cat 2	Cadmium sulphide	Carc Cat 2
Cobalt sulphate	Carc Cat 2	Lead compounds	Repr Cat 1

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Substances

Metal / product	Chemically modified	→	Used ‘as is’ or transformed
Intermediate	Chemically modified	→	Totally transformed
Ores and concentrates	No chemical modification	→	Totally transformed
Mineral	No chemical modification	→	Used ‘as is’

EU border

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Status

- Status depends on use, not the substance.
- Same substance can have more than one status
  - Matte that is dissolved in the EU is an intermediate.
  - Matte that is turned to blister is not.
  - Zinc used as Zn metal is not an intermediate.
  - Zn metal used to make Zn oxide is an intermediate.
- Data requirements etc depend on status and use, not substance.

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Important definitions

- Intermediate status is possible if a substance is chemically transformed into another substance.
- Unfortunately alloys are not defined as substances (preparations). Therefore anything that is used in the next processing step to make an alloy can not be an intermediate.
- Intermediates must be adequately controlled.

Commodity associations

- Work through Commodity associations.
- Can not envisage circumstances where it is better to go it alone.
- Financial benefits to working together
  - Reduced fees.
  - Data and dossier costs shared.
- Common classifications.

Commodity associations

- In most cases European commodity associations are working closely with the International bodies.
- Co-ordination, through umbrella bodies, e.g. Eurometaux, Eurofer etc.
- Requirements are reasonably well understood. – some aspects still unclear.
- Much effort for EU based organizations, but non-EU also considered and catered for.

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Status of Commodity Associations

- Are looking at setting up stand alone consortia to deal with REACH.
- Ultimate decisions driven by consortia members.

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Base metals

- Well catered for, much activity and data.
- Active programmes.
- Should not have any significant problems with compliance.
- Cu, Ni, Co, Pb, Cd, Zn etc

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Zinc activities

- IZA is coordinating a zinc consortium
  - Subgroup 1 Zn Metal and alloys
  - Subgroup 2 Zn compounds
  - Subgroup 3 Isolated transported Intermediates
- IZA Europe to do day to day management.
- First general Assembly of consortium members on 4 September in Brussels.

Contact person

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Summary

- Find out what you export and how it is done.
- Only Representative?
- Contact and work with commodity associations.
- You are better off being part of the process.
- Understand exactly what you are shipping.
- Classification is very important.
- Time is short.

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Definitions

- **Substance:** A chemical element and its compound in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.
- **Preparation:** A mixture or solution composed of two or more substances that have been intentionally blended together. The physiochemical, toxicological, ecotoxicological etc properties of the preparation are the same as those of the constituent substances.

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Definitions

- **Special Preparation:** Similar to a preparation, however the physiochemical, toxicological, ecotoxicological etc properties of the special preparation are different from those of the constituent substances (in a preparation they are the same). I.e. the constituent substances have undergone chemical modification to form the special preparation.
  Substances which occur in nature: Naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means.

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Definitions

- **Not chemically modified:** A substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities.

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