



Agenda Item 3

CX/NFSDU 11/33/4

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES
Thirty third Session
Bad Soden am Taunus, Germany
14 – 18 November 2011**

**PROPOSED DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR
LABELLING PURPOSES IN THE CODEX GUIDELINES ON NUTRITION LABELLING**

Review of existing daily vitamin and mineral intake reference values

(Prepared by FAO and WHO)

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1. BACKGROUND

At the 25th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) held in 2003, the CCNFSDU decided that there was a need to update the Nutrient Reference Values (NRVs) for labelling purposes in the Codex Guidelines on Nutrition Labelling (CAC/GL 2-1985). These Guidelines were previously amended in 1993 according to the recommendations of the FAO/WHO Expert Consultation held in Helsinki, Finland in 1988.

At the 29th Session in 2007, CCNFSDU agreed that the scope of the update should be limited to vitamins and minerals. In 2008, the 31st Session of the Codex Alimentarius Commission endorsed the proposal for new work which set out, as a first step, the establishment of general principles for NRVs for vitamins and minerals for the general population (older than 36 months of age), followed by development of principles and NRVs for the age group of 6 - 36 months.

CCNFSDU agreed to progress work through a Physical Working Group (PWG) chaired by the Republic of Korea and co-chaired by Australia. The PWG met immediately prior to the 32nd Session in Santiago, Chile, in 2010 and prepared a discussion paper. The aim of the discussion paper was to assist the development of additional or revised NRVs for labelling purposes in the Codex Guidelines on Nutrition Labelling. The delegation of Australia, on behalf of the working group, reported to the 32nd Session that the PWG agreed to proceed and derive the potential NRVs according to amended or new draft General Principles for vitamins and minerals and to note the substance of those draft principles in the report of the PWG. Additionally, the PWG considered whether the potential NRVs calculated from FAO/WHO recommended nutrient intakes (RNI) would be suitable with respect to their scientific basis; however, a consensus on that topic was not reached because of a lack of data.

The 32nd Session of CCNFSDU, therefore, requested the WHO/FAO to review existing daily vitamin and mineral intake reference values globally for a list of 28 vitamins and minerals and the basis for those values for an apparently healthy population of adult males and adult females (See **Annex I** for complete request). WHO/FAO were requested to provide a report to the 33rd Session CCNFSDU to be held in Bad Soden am Taunus, Germany, 14 -18 November 2011.

The request of the 32nd Session of CCNFSDU consisted of two parts. The first part was to provide a comparison of nutrient recommendations from recognized authoritative scientific bodies and from WHO/FAO taken from reference sources published after 1998. The second part was to provide an estimate of the extent of the change in the scientific evidence base since 1998 for the vitamins and minerals of interest.

2. METHODS

2.1 Compilation of existing daily vitamin and mineral intake reference values and their basis

To collect existing NRVs from countries around the world, the WHO/FAO executed a multi-faceted approach to data collection which included: 1) retrieving data from available databases and contacting original sources of that data to collect additional information, 2) contacting Member Countries through WHO/FAO Regional and Country Offices, and 3) sending out a Call for Data through the Codex Secretariat and disseminating the call for data through existing WHO/FAO networks.

2.1.1 Retrieving previously compiled data and contacting original sources for additional details

WHO/FAO contacted the Network of EUROpean micronutrient RECommendations Aligned (EURRECA) which manages a database, known as Nutri-RecQuest, that contains the NRVs of 29 micronutrients from countries, organizations and entities, the majority of which are found in Europe. The data available in Nutri-RecQuest on the 28 vitamins and minerals of interest to CCNFSDU were compiled in an excel spreadsheet made specifically for collecting all details requested by CCNFSDU. Once the numeric values and citations for original data available from Nutri-RecQuest were entered, the original data source (e.g. published reports, peer-reviewed scientific manuscripts, legal documents) found in Nutri-RecQuest were retrieved in order to verify the data and to supplement the data with all details requested by CCNFSDU. If upon retrieval of the original data source, details were still incomplete, WHO/FAO contacted the countries directly to request additional information. In these cases, the WHO/FAO sent the country a template containing all the data available from Nutri-RecQuest and other available materials and requested that the country complete the remaining details.

2.1.2 Collecting data from Member Countries through WHO/FAO Regional and Country Offices

WHO Headquarters relayed the request for information petitioned by the CCNFSDU to all six WHO Regional Offices. WHO Regional Offices then contacted WHO Country Offices to request data from their respective counterparts in the Ministry of Health, National Institute or other relevant agencies and institutions. WHO Headquarters also sent emails to the members of the WHO Global Network of Institutions for Scientific Advice on Nutrition and to other international partners in nutrition requesting data. FAO contacted its Food and Nutrition Officers in the FAO Regional office in Bangkok and Sub-regional office in Budapest. These officers obtained information from the authorities in several countries.

All data were to be sent directly via email or via postal mail to either the WHO Headquarters in Geneva, Switzerland or the FAO Headquarters in Rome, Italy. The WHO and FAO maintained constant communication to ensure that all data received were entered in the excel spreadsheet data collection form in a timely and complete manner. If upon receipt of data from countries or partners, details were incomplete, WHO/FAO followed-up with the countries to request additional information. In these cases, the WHO/FAO sent the country a template containing all compiled data and requested that the country complete the remaining details.

2.1.3 Issuing the Call for Data

On 27 June 2011, a Call for Data was issued by the Codex Secretariat to Codex contact points in all Codex Member Countries and observers. The Call for Data included the request to WHO/FAO by the CCNFSDU, the details of the data being requested, the contact information and instructions for sending data to WHO/FAO, and the deadline for submission of data (15 August 2011). The Call for Data was also disseminated by WHO and FAO through electronic mailing to existing nutrition mailing lists (i.e. WHO nutrition partners' mailing list, WHO micronutrients mailing list) and to international partners. The Call for Data was also posted on the WHO and FAO websites.

All data received before the deadline were compiled in the excel spreadsheet data collection form. All attempts were made to also include data received after that deadline when received in a sufficiently timely manner. If upon receipt of data from countries or partners, details were incomplete, WHO/FAO followed-up with the countries to request additional information. In these cases, the WHO/FAO sent the country a template containing all compiled data and requested that the country complete the remaining details.

2.1.4 Data summary and analysis

We first generated summary statistics including the number of countries from which data were collected and the regional distribution of data; number of nutrients for which information was collected; and number of details for which data were available. We then summarized data in tables by countries which utilize NRVs generated by WHO/FAO or other countries or scientific bodies, countries which adapt NRVs from these sources, or countries which generate and utilize unique NRVs for their country. These data were summarized by nutrient. The results are presented in narrative, tabular, and graphic form.

2.2 Literature search to evaluate change in scientific evidence base since 1998

As an indicator of the change in the scientific evidence base, we quantified the number of peer-reviewed scientific manuscripts which have been published since 1998 on each of the vitamins and minerals of interest. On 11 July 2011, we conducted a literature search of the PubMed bibliographic database comprised of more than 21 million references to journal articles in life sciences and online books. A separate search was conducted for each nutrient. The search term was the English name of the nutrient and was limited to its appearance in the title or abstract of the citation. In the case of pantothenate and folate, these common names and the names of the acid (i.e. pantothenic acid and folic acid) were used in the search terms. Additionally the search term for Chromium+3 was the common name Chromium. Searches were also limited to manuscripts involving humans which had a publication date of 1998 to 11 July 2011. The total number of citations found, the number of citations which were review articles, the number of citations which were not review articles, and the number of citations which were randomized, controlled trials were summarized for each nutrient.

3. RESULTS

3.1 Results of compilation of existing daily vitamin and mineral intake reference values and their basis

3.1.1 Descriptive Results

Data on nutrient reference values were collected from 55 countries. Of the countries included in this report 31 are located in the United Nations defined region of Europe, 12 in Asia, 8 in the Americas, 3 in Oceania and 1 in Africa. The regional distribution of countries that responded or had accessible data is provided in **Table 1**. All 28 nutrients had values from at least one country. Calcium, Iron, Riboflavin, Vitamin A and Vitamin C had the most values reported, with 53 countries, or 96%, providing values. Chloride had the fewest values reported with 17 countries or 31% followed by Chromium and Molybdenum both of which had 22 countries, or 40%. Complete results on the number of countries with values for each nutrient are found in **Table 2**.

As described in the Methods section above, numerical values for country NRVs were obtained from Member Countries who had responded to the Call for Data issued by WHO/FAO and also through the WHO/FAO Regional and Country Office network, as well as through available published books or manuscripts which we have identified through searches and verifications. Numerical values were also obtained through the NutriRecQuest database maintained by EURRECA, and these values were further verified through directly communicating with respective countries or through investigation of the original sources whenever possible.

Data other than the numerical values of the NRVs were collected from reference documents provided by countries and through direct communications with countries. Details on physiological endpoints, reference body weights and other variables of interest as requested by the 32nd CCNFSDU were more difficult to obtain and were collected mainly for those countries that were able to supply WHO/FAO with complete published versions of their nutrient recommendations. Detailed information of the variables of interest can be found in the excel data compilation spreadsheet which is posted at <ftp://ftp.fao.org/codex/ccnfsdu33/NRVreport.xls>

Table 1. Regional distribution of countries

| United Nations Region | Number of countries that responded or had accessible data | Countries |
|------------------------------|--|---|
| Africa | 1 | Zimbabwe |
| Americas | 8 | Argentina, Plurinational State of Bolivia, Brazil, Canada, Colombia, Cuba, Mexico, the United States of America |
| Asia | 12 | China, Georgia, India, Israel, Japan, Kuwait, Malaysia, Mongolia, Oman, the Philippines, Republic of Korea, Thailand |
| Europe | 31 | Albania, Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Denmark, Estonia, Finland, the Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Montenegro, Norway, Poland, Portugal, Romania, the Russian Federation, Slovakia, Slovenia, Spain, Sweden, Switzerland, the Netherlands, the United Kingdom of Great Britain and Northern Ireland |
| Oceania | 3 | Australia, New Zealand, Samoa |

Table 2. Number of countries providing values for each nutrient

| Nutrient | No. of countries with a value | Percentage of responding countries (n=55) with a value |
|-----------------|--------------------------------------|---|
| Calcium | 53 | 96% |
| Iron | 53 | 96% |
| Riboflavin | 53 | 96% |
| Vitamin A | 53 | 96% |
| Vitamin C | 53 | 96% |
| Thiamin | 52 | 95% |
| Folate | 51 | 93% |
| Iodine | 51 | 93% |
| Niacin | 51 | 93% |
| Vitamin B12 | 51 | 93% |
| Vitamin D | 51 | 93% |
| Magnesium | 49 | 89% |
| Vitamin B6 | 49 | 89% |
| Vitamin E | 49 | 89% |
| Zinc | 49 | 89% |
| Phosphorous | 48 | 87% |
| Selenium | 47 | 85% |
| Copper | 44 | 80% |
| Potassium | 35 | 64% |
| Sodium | 35 | 64% |
| Fluoride | 29 | 53% |
| Vitamin K | 28 | 51% |
| Manganese | 27 | 49% |
| Pantothenate | 26 | 47% |
| Biotin | 24 | 44% |
| Chromium | 22 | 40% |
| Molybdenum | 22 | 40% |
| Chloride | 17 | 31% |

3.1.2 Summary tables of main finding by nutrient

The summary results of the main findings are found in graphical form in **Annex II**. For each nutrient there is a pie chart displaying the source of the reference value for all countries from which data were collected. Countries that utilized exact values developed by another country or organization and the countries or organizations providing those values are listed in the tables corresponding to each pie chart. Two countries, Kuwait and Samoa, reported not having any values specific to the country. Several countries reported using the values recommended by the FAO/WHO, while others frequently utilized the values developed by the United States and Canada.

The bar graphs display the NRVs of only those countries with original values developed by scientific bodies within the country or with values based on methods provided by another country but modified by a scientific body in the country or with values of unclear origin. Information regarding the source of each value was obtained on a nutrient by nutrient basis, as several countries developed original values for certain nutrients and utilized exact values from other countries or modified values from other countries for other nutrients depending on available research. Horizontal lines indicate the Codex labelling value and the values recommended by the FAO/WHO. The bar graphs are organized according to United Nations defined region and type of NRV (individual nutrient level at 98 percentile (INL98), adequate intake (AI), or unclear) and are gender specific with the top graph always being for men and the bottom graph always for women.

Some nutrients have little variation in values, for instance Iodine values range from 124-200 μ g for men and 110-200 μ g for women. Other nutrients, for example copper, show a greater variation and range of values with a range of 800-3000mg for men and 700-3000mg for women. While only 13 countries had original or modified values for Biotin, the values varied significantly. The lowest value for biotin was 30 μ g while the highest reported value was 150 μ g, a 5 fold difference.

3.2 Results from Literature Search

The results of the literature search of the PubMed bibliographic database to evaluate change in scientific evidence base since 1998 are displayed in **Figure 1**. The search conducted for calcium provided the greatest number of peer-reviewed scientific manuscripts with 59,390, followed by Sodium and Iron with 37,520 and 25,994 respectively. The search for Pantothenate resulted in the least number of peer-reviewed manuscripts with 290 total papers. Thiamine and Phosphorous also had few results with 345 and 477 total papers in that order.

Limiting the search to only original articles and excluding reviews showed a similar pattern. Further limiting the search to include only randomized controlled trials also resulted in a comparable trend.

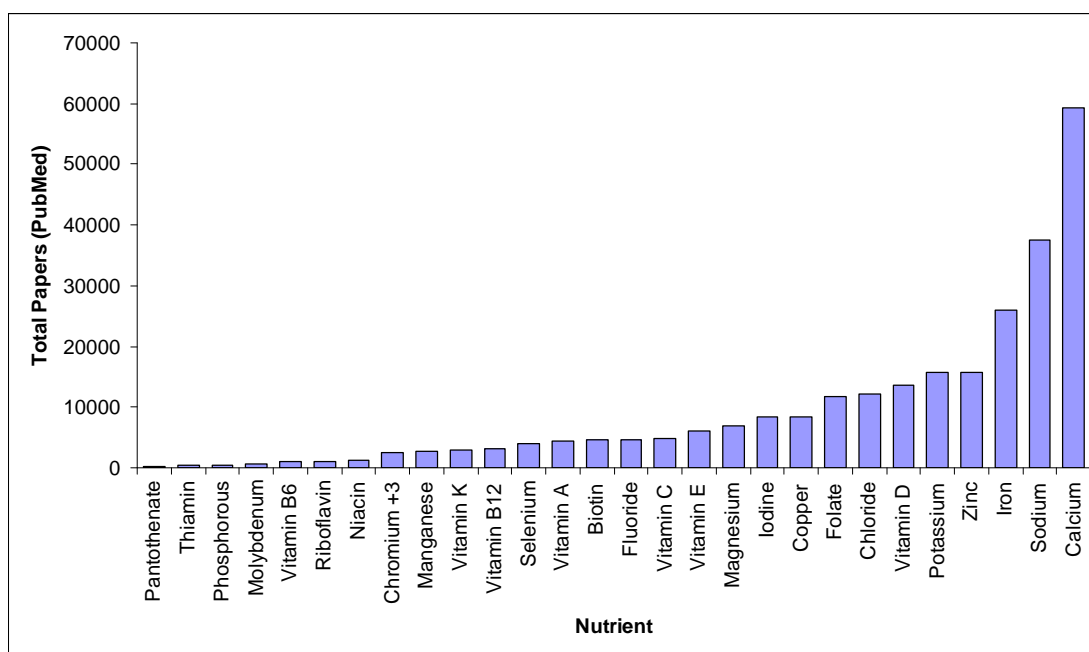


Figure 1. Results of the literature search to evaluate change in scientific evidence base since 1998. The figure shows the number of peer-reviewed scientific manuscripts within the PubMed database that have been published since 1998 on each of the nutrients of interest in order of least to greatest number of publications.

4. DISCUSSION

4.1 Strengths and limitations of the review

The WHO/FAO received information from or were able to contact many countries or scientific bodies within countries directly to obtain primary sources of information. The data collected came from both developed and developing countries, and was representative of countries with various national income levels.

Challenges arose because of a lack of common terminology among the various countries. Many countries and scientific bodies use different terms to describe the same concept. Also many countries and scientific bodies use the same term to describe different concepts. A weakness of this review is that in order to classify and present the data, terms with varied definitions were categorized into one of three conditions. For the purposes of this review, values were categorized as either an INL98, AI, or unclear.

INL98 is used as an umbrella term to include nutrient intake values which are intended to cover the needs of most of the population. AI is used to describe values intended to be a safe or adequate for an average adult. Some countries provided more qualitative definitions of concepts, making it difficult to categorize the NRV. Often, it was a challenge to determine the type of recommendation or source of the value and several had to be classified as unclear. For a large number of countries, numerical values were easily obtained; however, other variables of interest, such as physiological endpoint and reference body weights used to develop NRVs were more difficult to acquire.

Several countries were able to provide complete published versions of their nutrition recommendations in book form. When countries provided such a reference, most variables of interest could be extracted from the reference and compiled. Some countries, however, were only able to provide numerical data without detailed information on the derivation of the NRV. Despite the multiple strategies used to collect data the African region was underrepresented with only one country for which data were collected while the European region had far more countries than other regions, i.e. 31 countries out of the 55 countries.

4.2 Summary of patterns, consistency and inconsistency

There were no notable regional differences for values of any nutrient. Dividing regions into smaller sub-regions may provide more information for detection of trends based on geographical area; however that would require the collection of data from more countries. The collection of data from more countries may also provide the data needed to detect regional-level trends currently limited by the limited representation from some regions. Nonetheless, one notable pattern based on geography was the relatively high recommendation for vitamin D intake in the Nordic countries likely due to limited winter sunlight. Additionally, the United Kingdom reported that for apparently healthy adults, the NRV for vitamin D is zero, indicating that the requirement for this nutrient could be met through appropriate exposure to the sun.

More countries reported having an NRV for those nutrients which were also found to have more published papers in the scientific literature since 1998. The higher number of published papers is indicative of both a greater scientific interest and a larger evidence base on which to formulate recommendations.

In most instances, if a country had an NRV for a nutrient they had an NRV for both males and females. It was noted that for males, there were generally more subdivisions of NRV by age category. This trend held true even after accounting for the fact that the data being collected for men were for men 19 - 65 years of age while those for women were for 19 - 50 years of age.

Annex I: Request made to WHO/FAO during 32nd session of CCNFSDU**PROPOSEDS DRAFT ADDITIONAL OR REVISED NUTRIENT REFERENCE VALUES FOR LABELLING PURPOSES IN THE CODEX GUIDELINES ON****NUTRITION LABELLING****REQUEST to WHO/FAO**

1. WHO/FAO are requested to provide a report to 33rd session of CCNFSDU, 2011 that details the results of a review of existing daily vitamin and mineral intake reference values and their basis as outlined below for an apparently healthy population of adult males (preferably aged 19-65 years) and adult females (preferably aged 19- 50 years) The report, through the presentation of information in tables, should provide a comparison of nutrient recommendations from recognized authoritative scientific bodies and from WHO/FAO. This information should be taken from data sources published after 1998 that reflect the Committee's second draft General Principle for selection of data sources *Relevant and recent values that reflect independent review of the science, from recognized authoritative scientific bodies other than WHO/FAO.*

The 28 vitamins and minerals are listed in the Table below.

The details should include, where relevant and available:

- The values themselves
- Applicable age ranges
- Physiological endpoints used to establish the INL50 or similar, or other measures such as AI and the reason for the choice
- Method of calculation of INL98 or similar from INL50 or similar including coefficients of variation
- Reference body weights and basis for extrapolation methods if used
- Determination of or assumptions about dietary bioavailabilities of the vitamin or mineral
- Conversion factors applied to provitamins, isomers or other relevant nutrients to units of equivalents such as niacin equivalents.
- Year that scientific evaluation was conducted
- Basis for the value i.e., primary evaluation or derivation from other countries' values

2 WHO/FAO are also requested to provide an estimate to 33rd session of CCNFSDU, 2011 of the extent of the change in the scientific evidence base since 1998 for the vitamins and minerals listed in the Table below. It is anticipated that an estimate could be done by a literature search on relevant scientific data bases using appropriate inclusion and exclusion criteria and counting the number of papers published since 1998. The report would document, for each vitamin and mineral, the number of papers found and the search strategy employed.

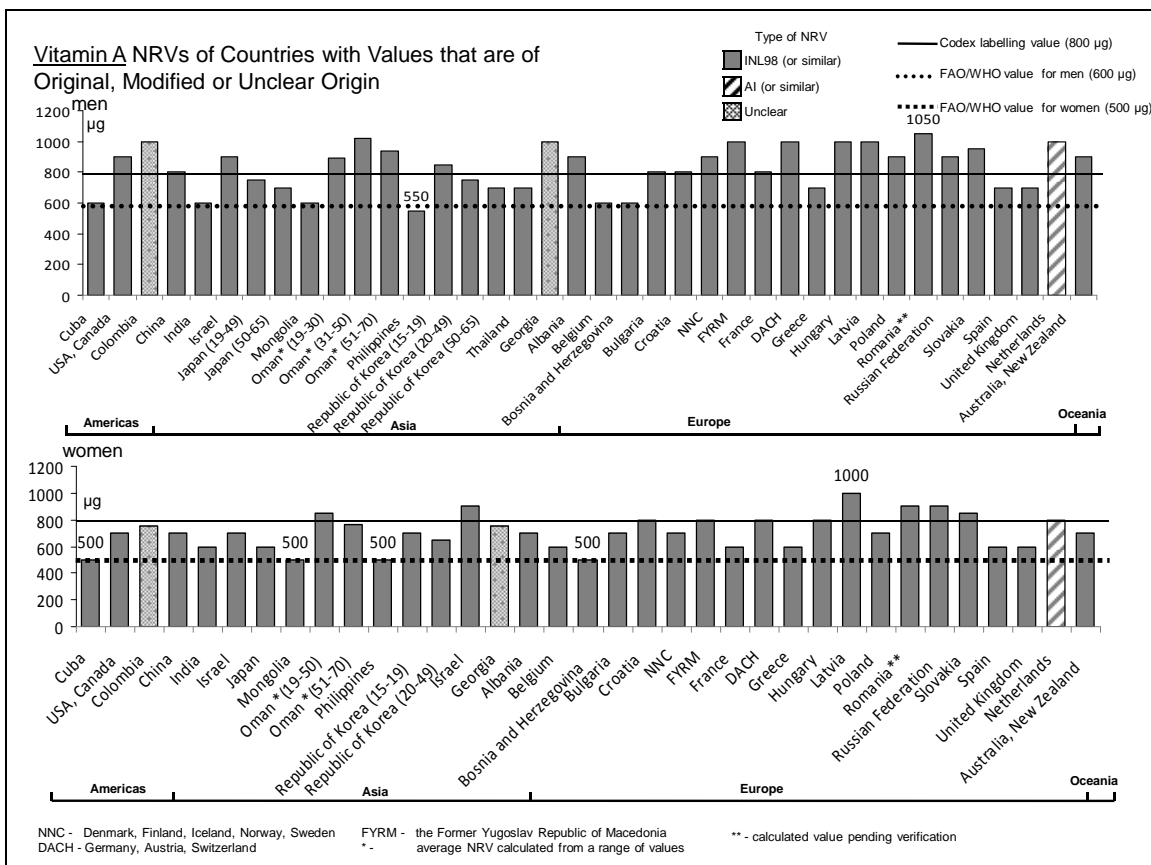
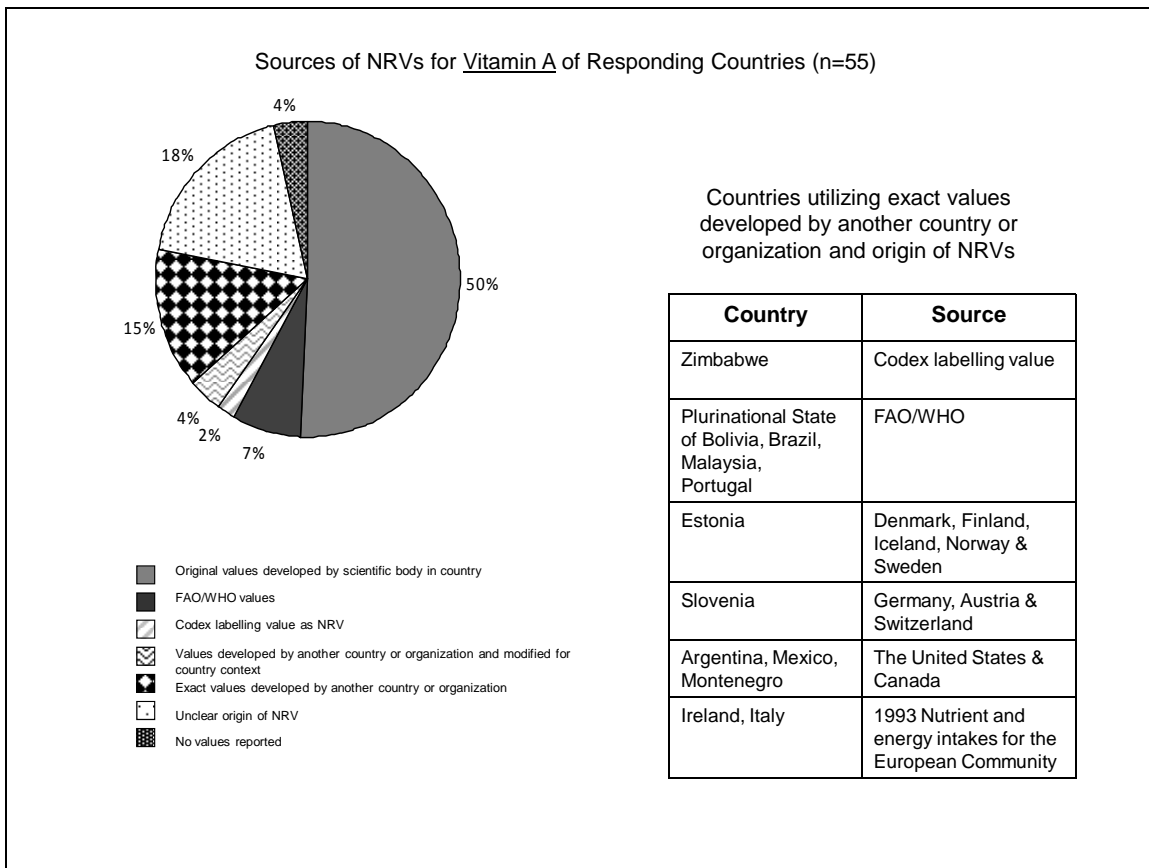
REQUEST to WHO

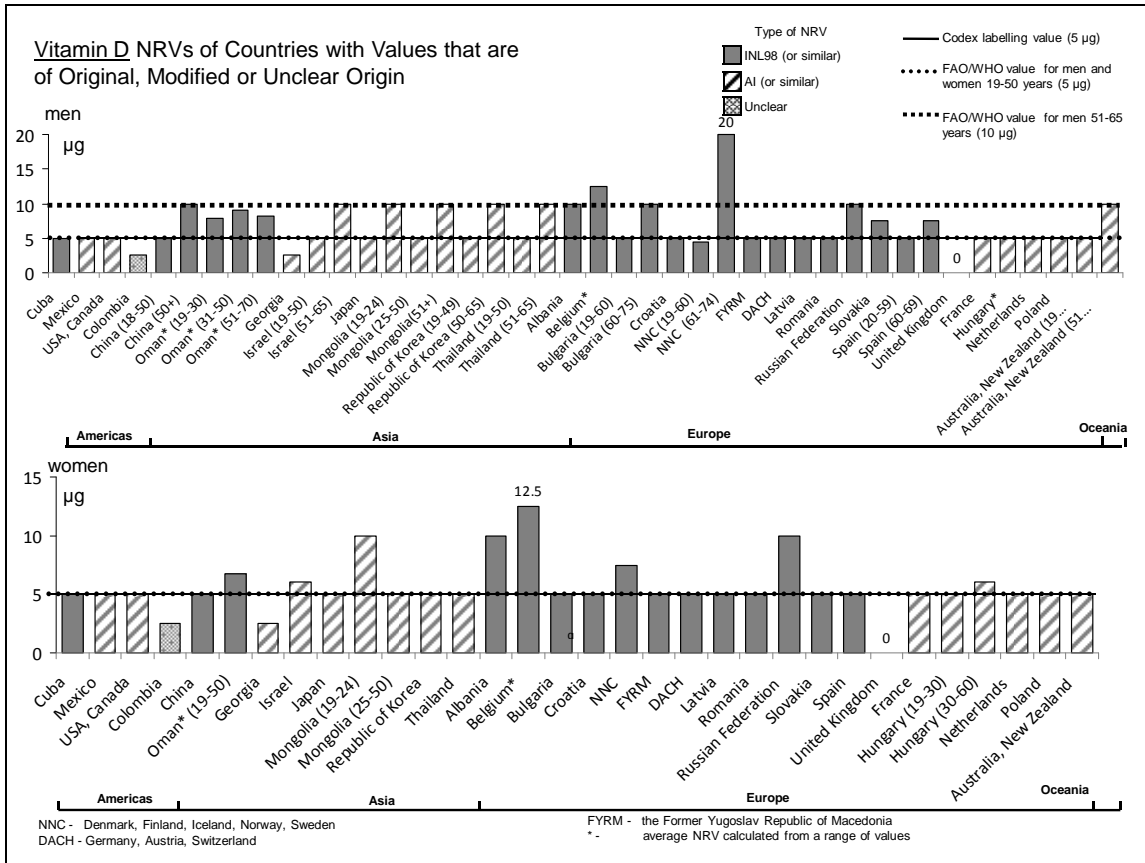
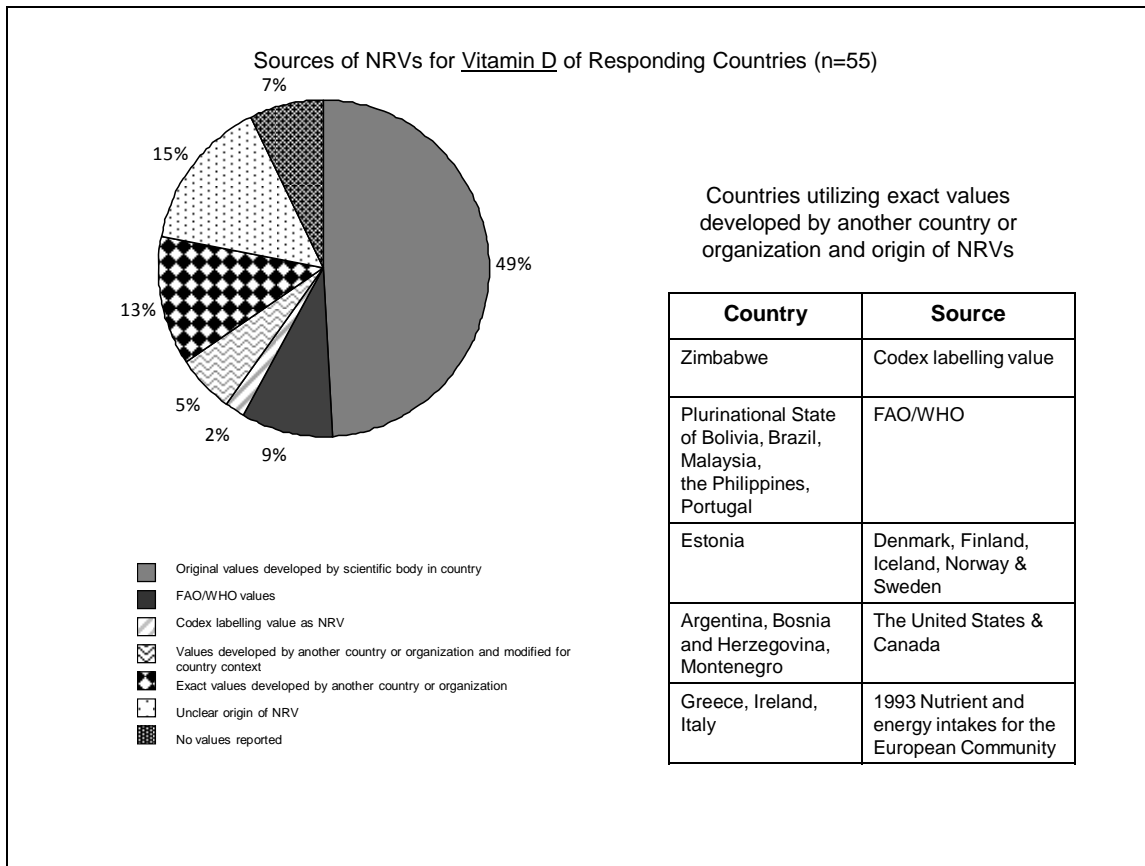
3 WHO may wish to consider the establishment of daily potassium intake values for the general population on the basis of dietary adequacy and/or reduction of chronic, noncommunicable disease risk as a part of its work on salt and sodium. This work is anticipated to be included in the forthcoming review of salt and sodium recommendations by the WHO Nutrition Guidance Expert Advisory Group (NUGAG).

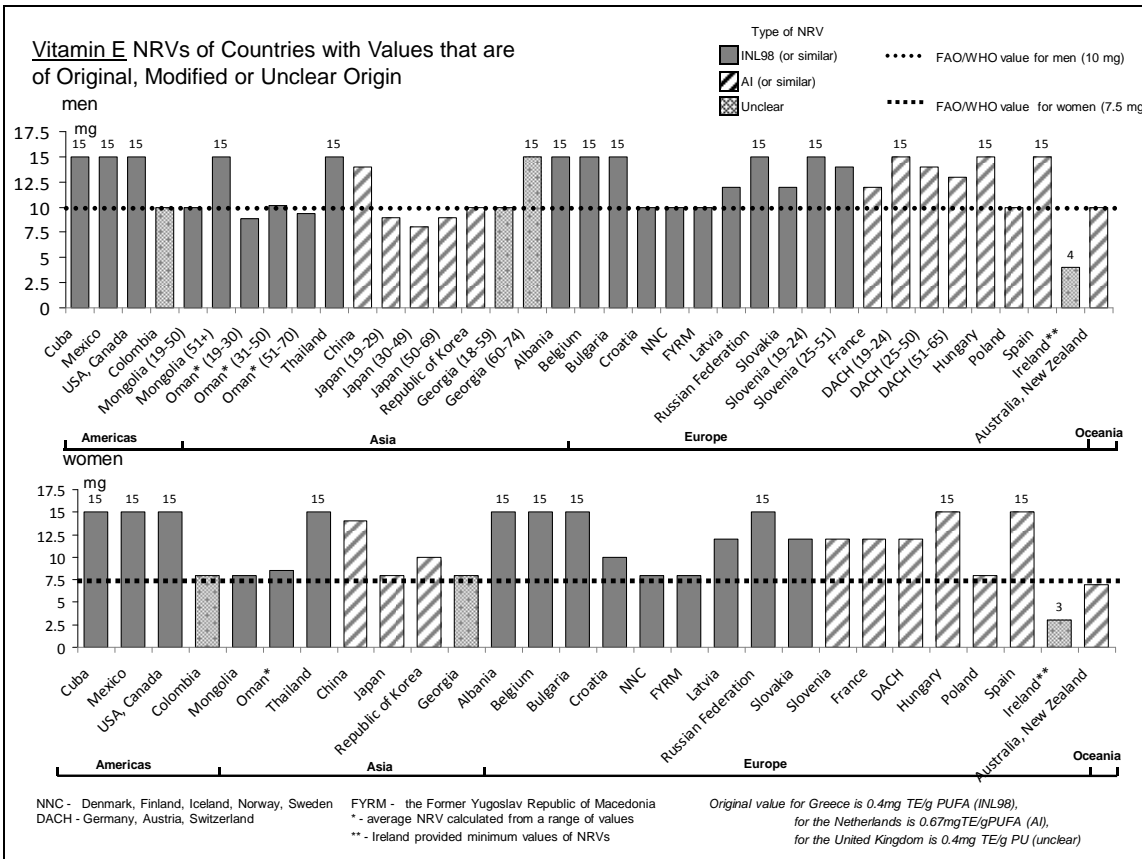
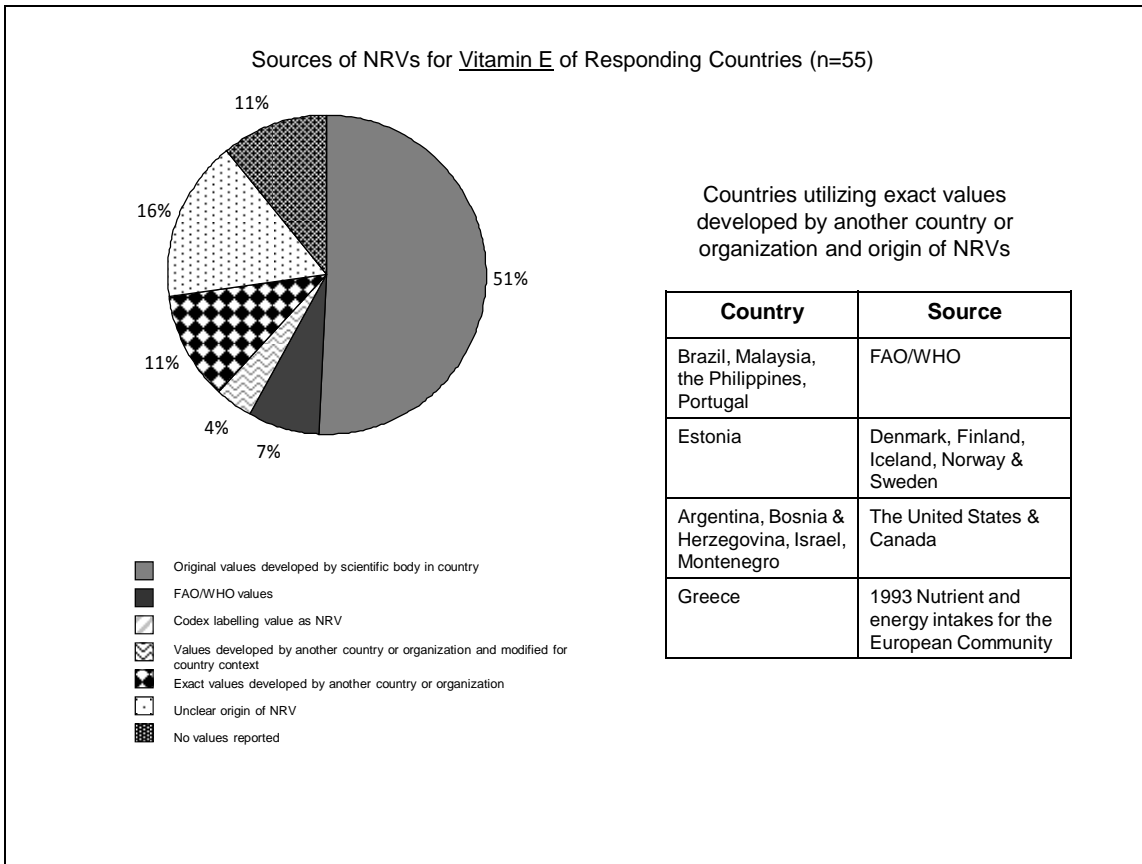
Vitamins and minerals requested to WHO/FAO

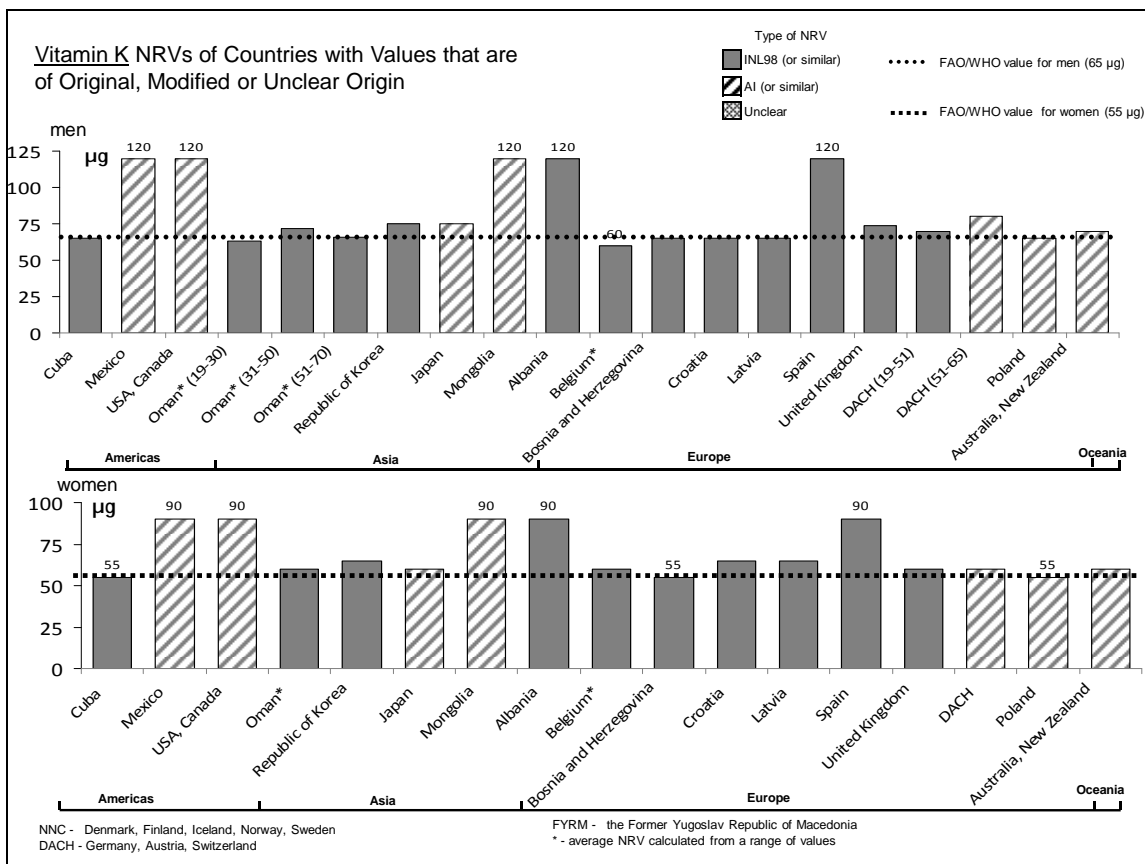
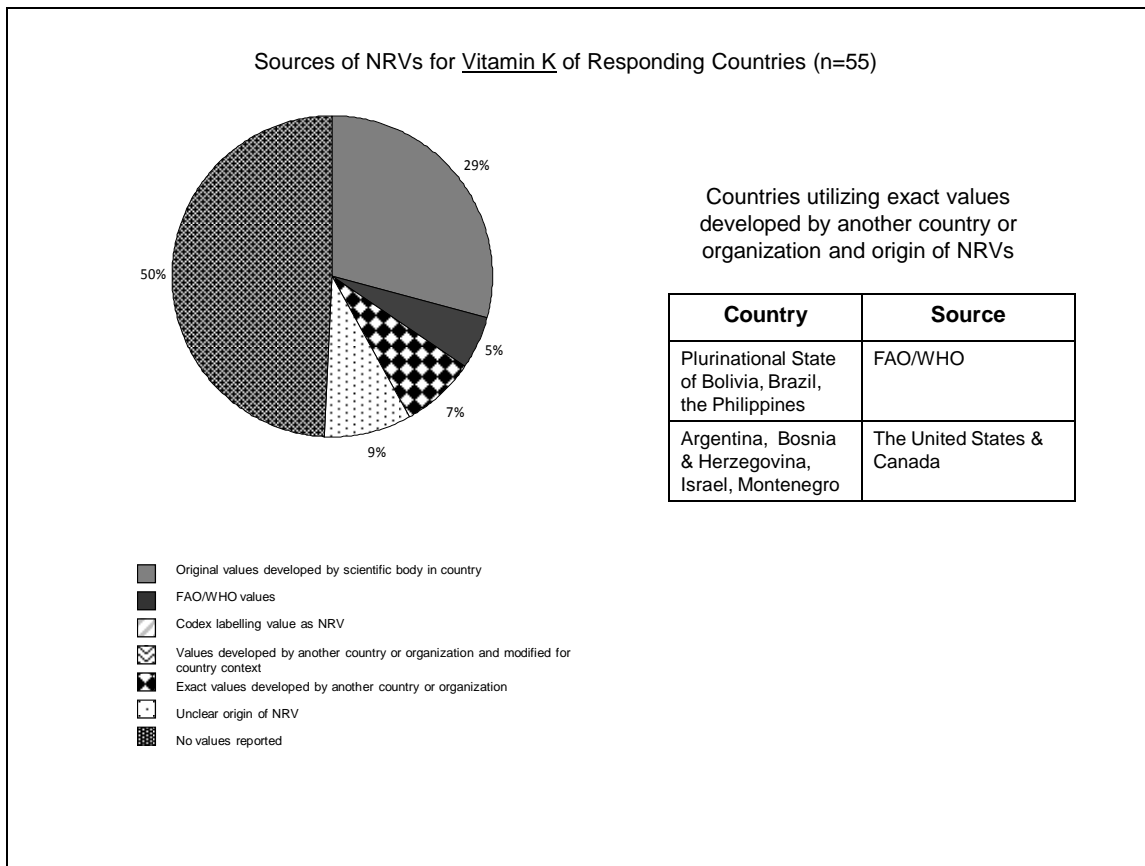
| Vitamins | Minerals |
|-----------------|-----------------|
| Vitamin A | Calcium |
| Vitamin D | Magnesium |
| Vitamin E | Iodine |
| Vitamin K | Iron |
| Vitamin C | Zinc |
| Thiamin | Selenium |
| Riboflavin | Copper |
| Niacin | Chloride |
| Vitamin B6 | Chromium (3+) |
| Foliar | Sodium |
| Vitamin B12 | Fluoride |
| Pantothenate | Manganese |
| Biotin | Molybdenum |
| | Phosphorus |
| | Potassium |

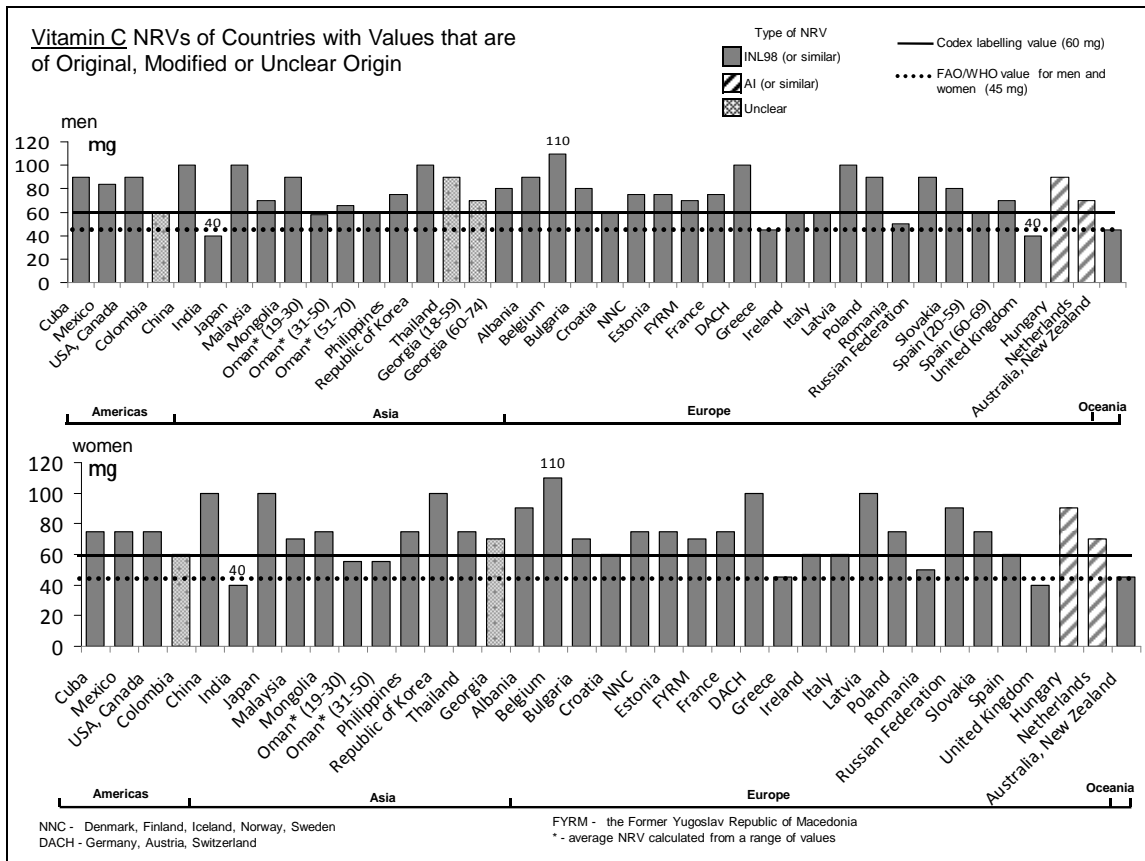
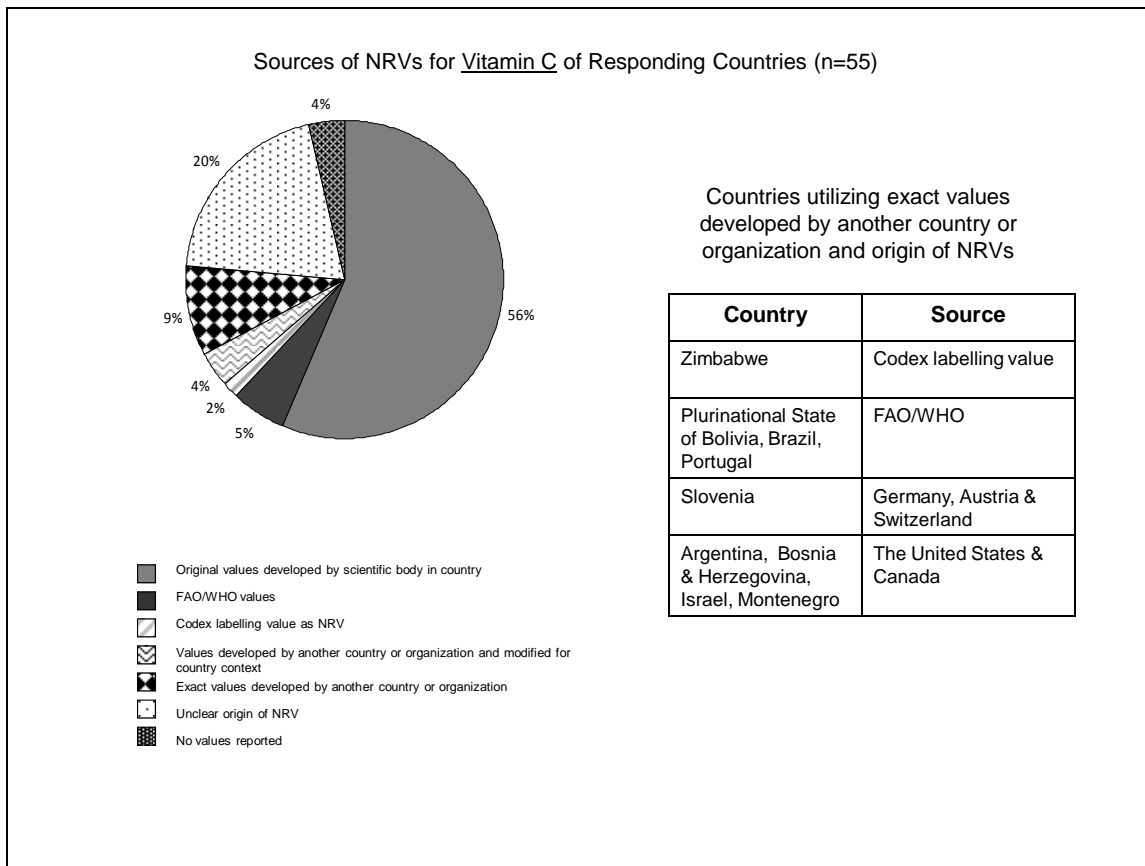
Annex II: Summary of main findings by nutrient

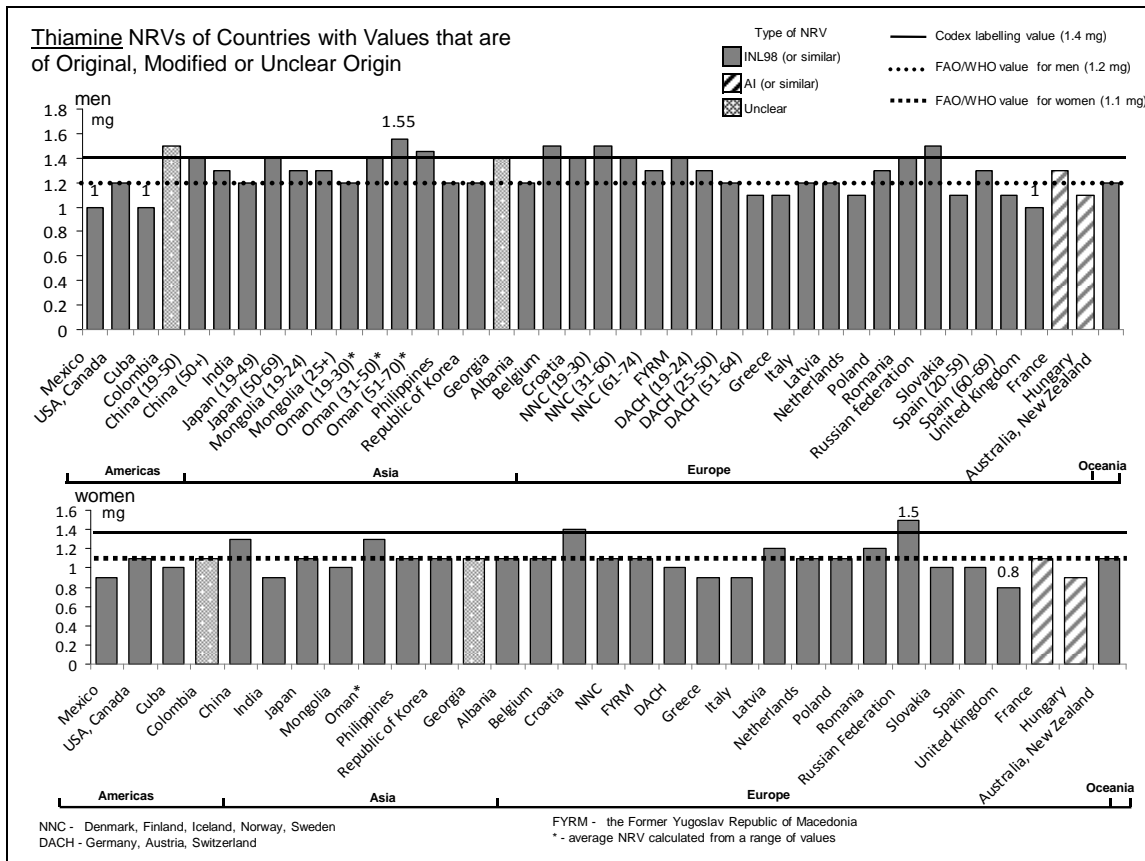
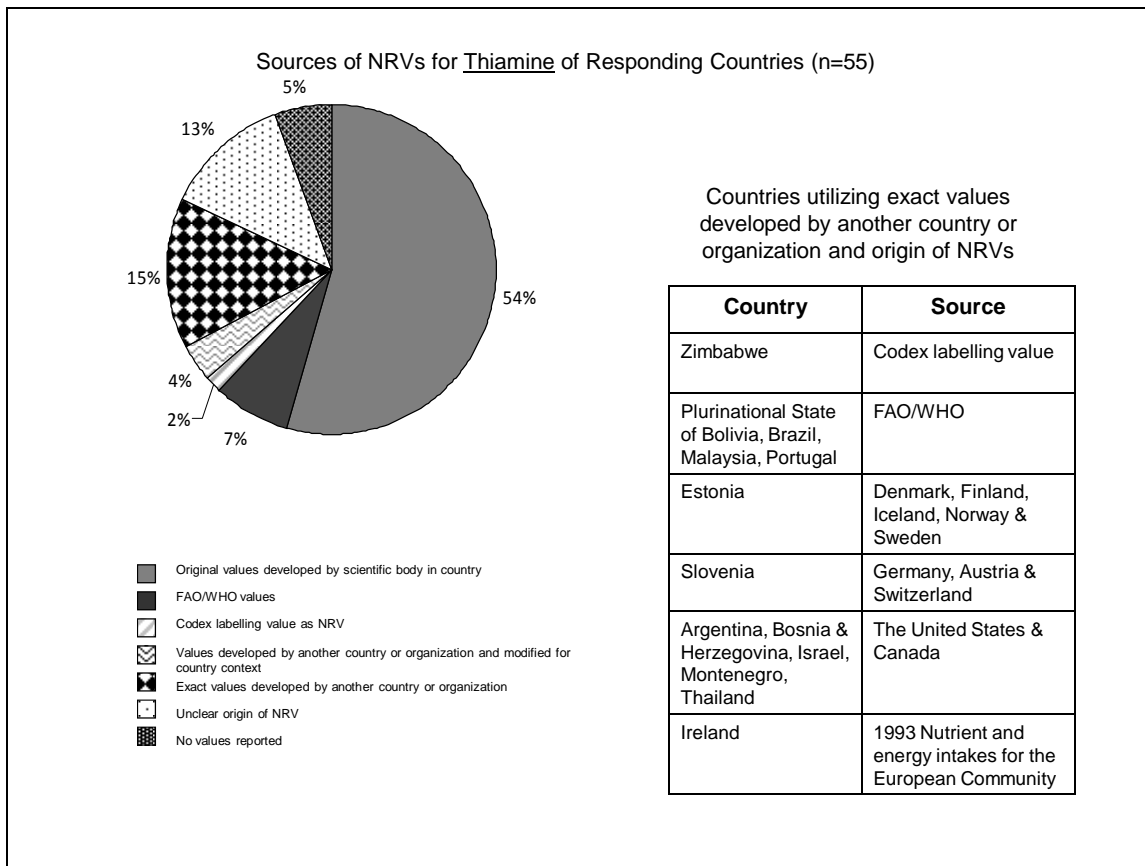


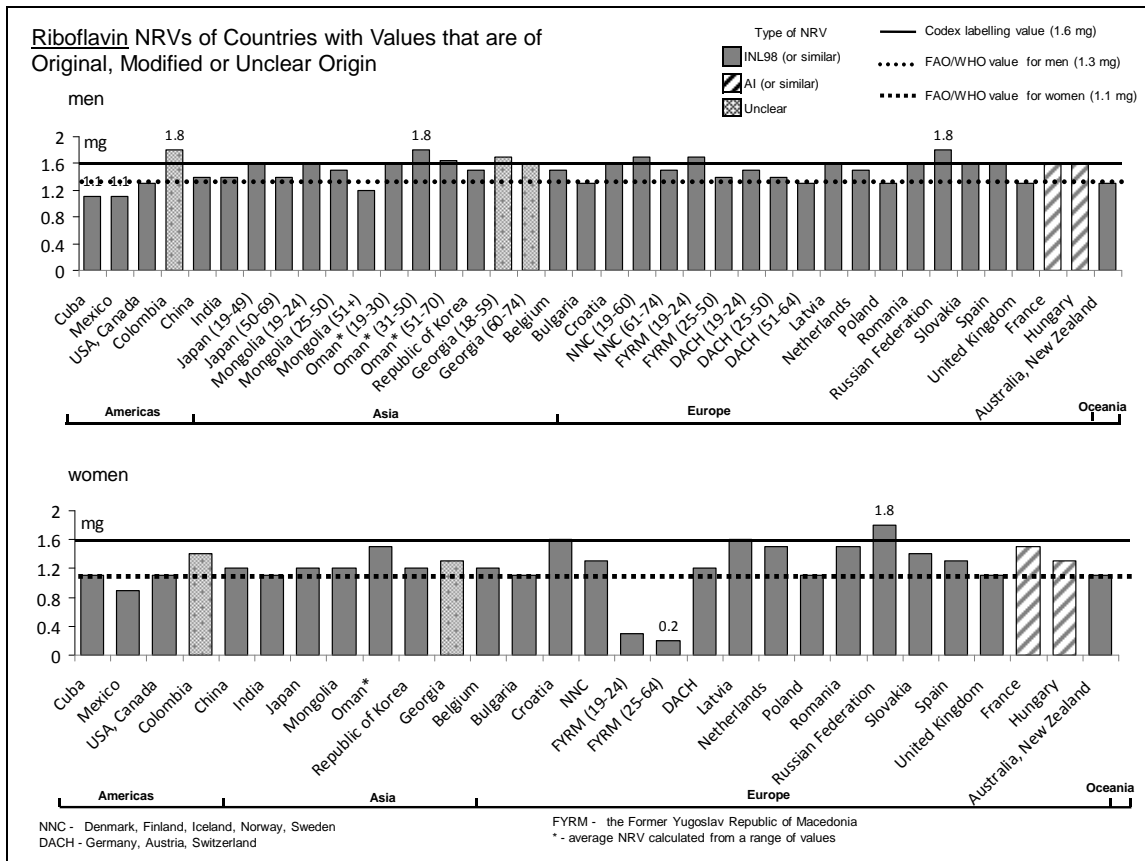
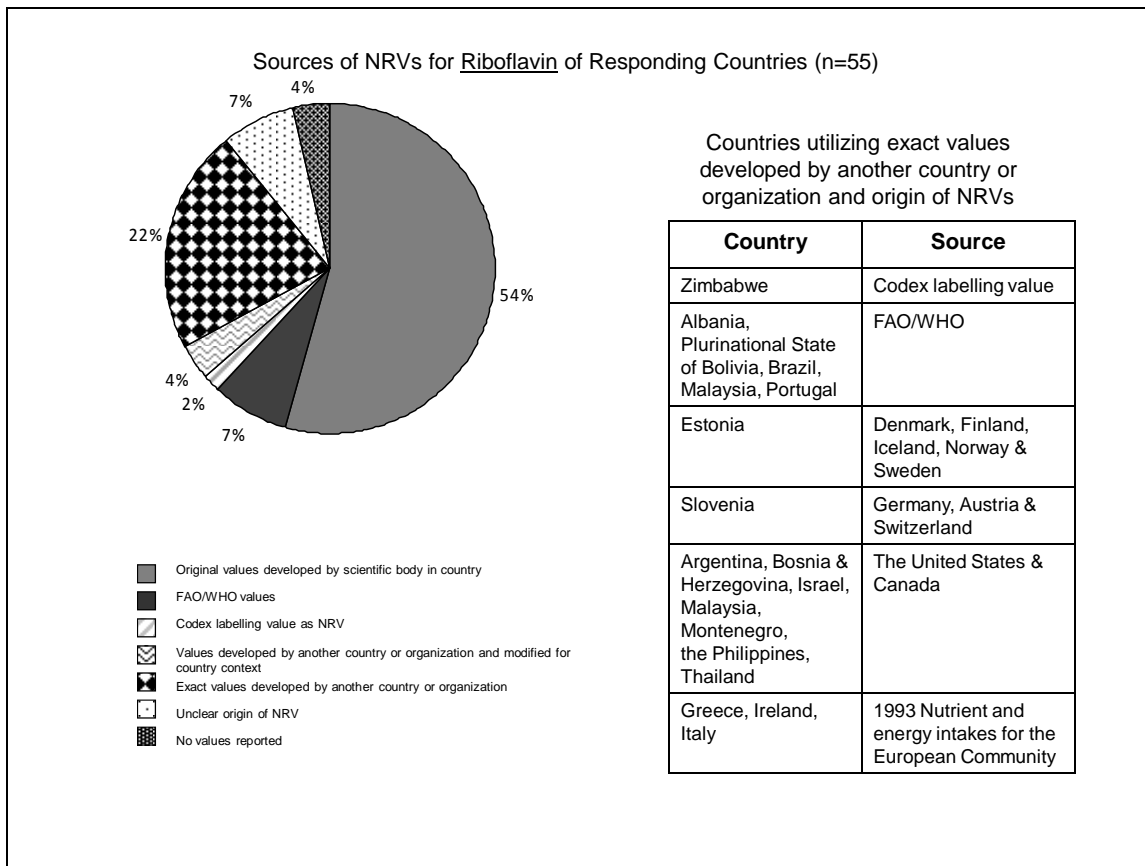


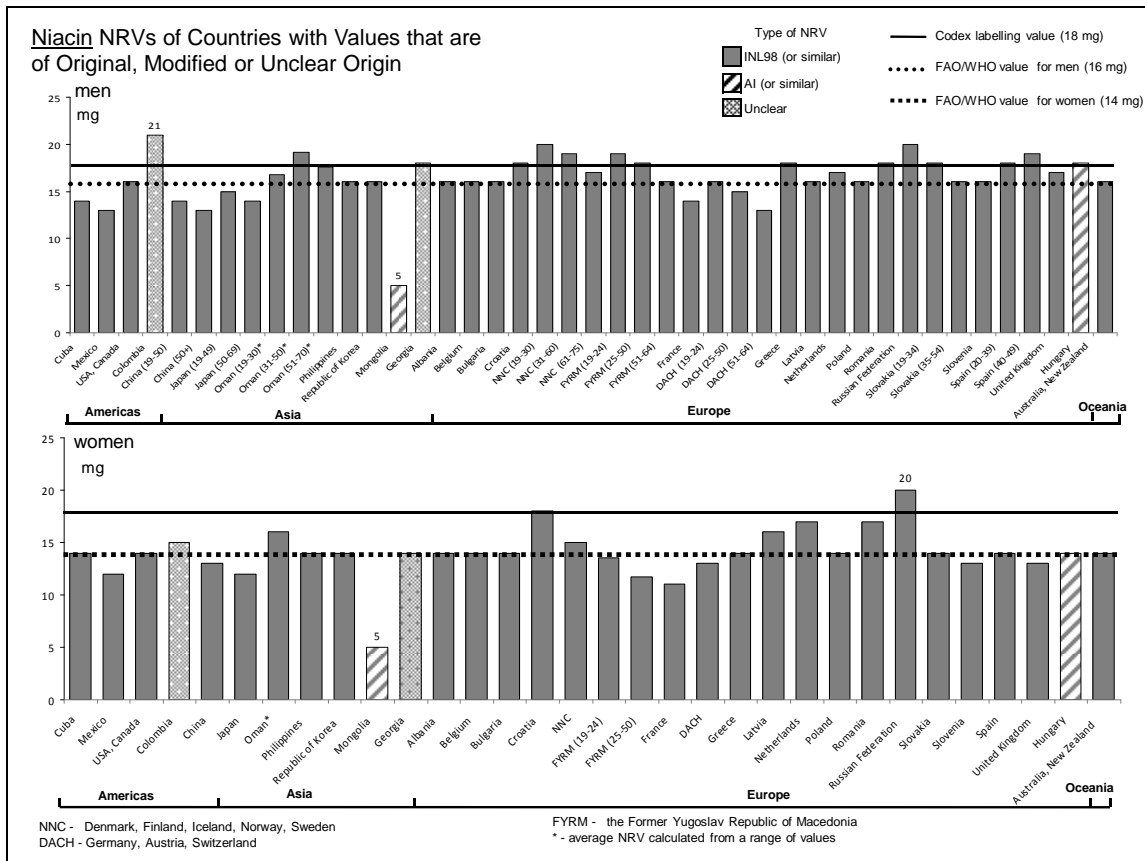
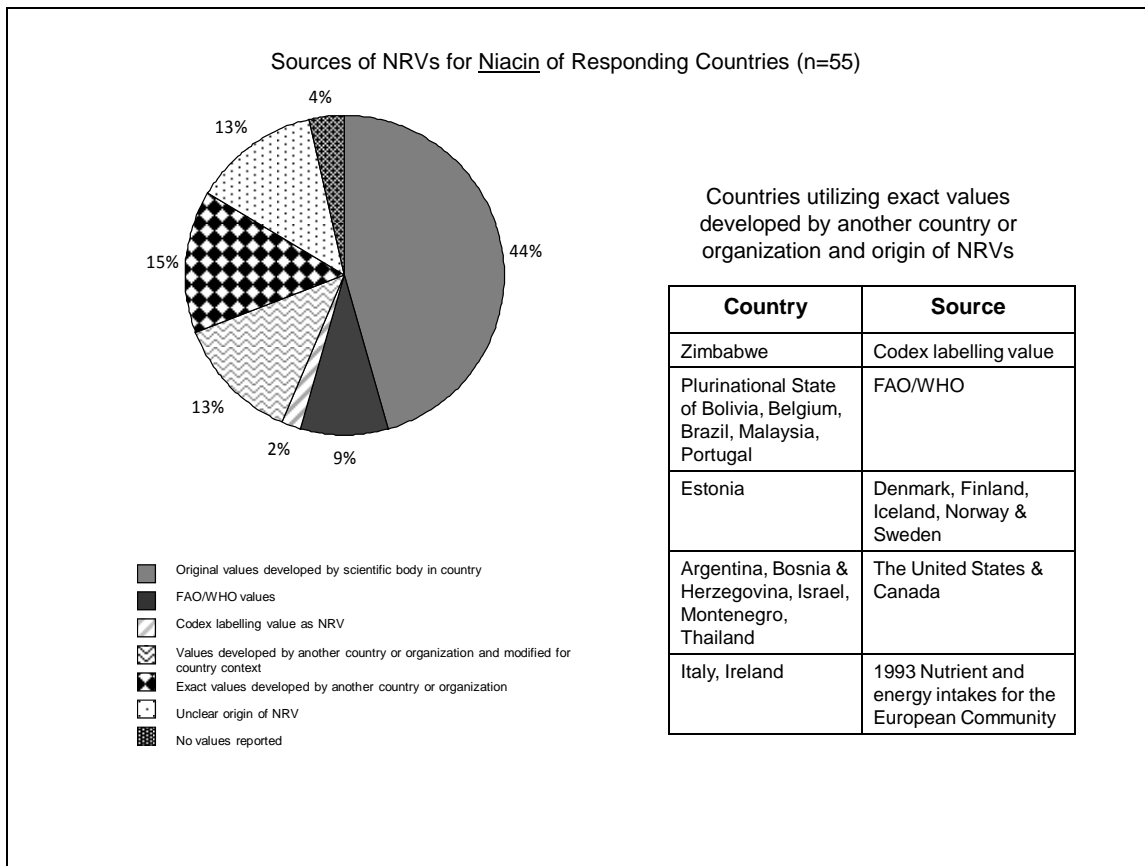


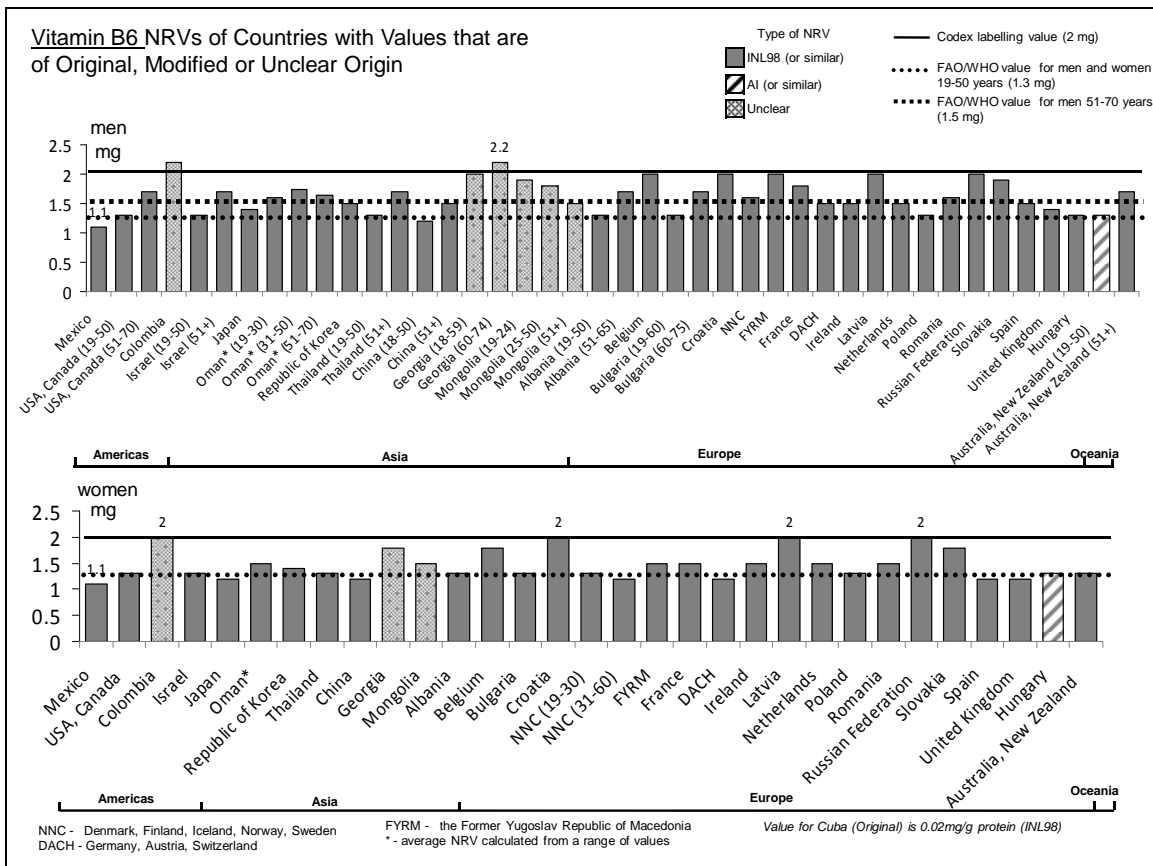
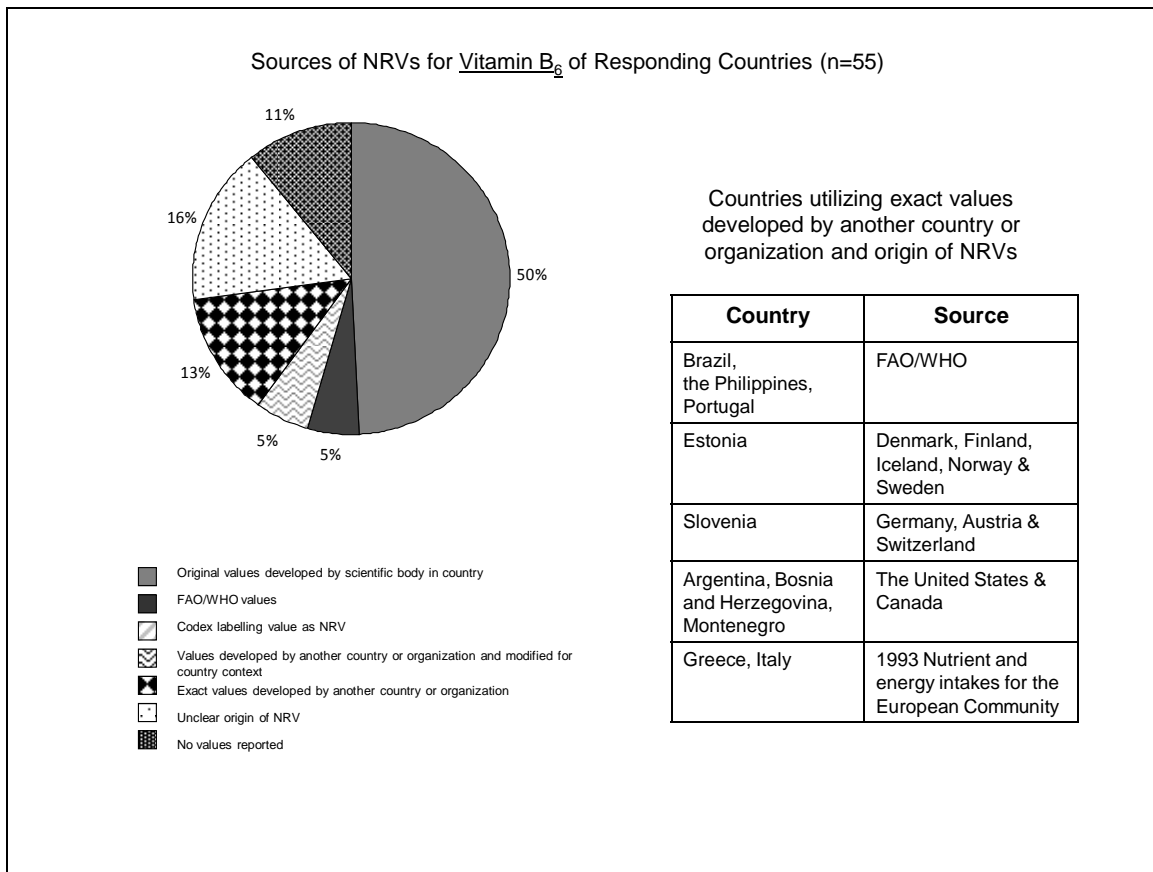


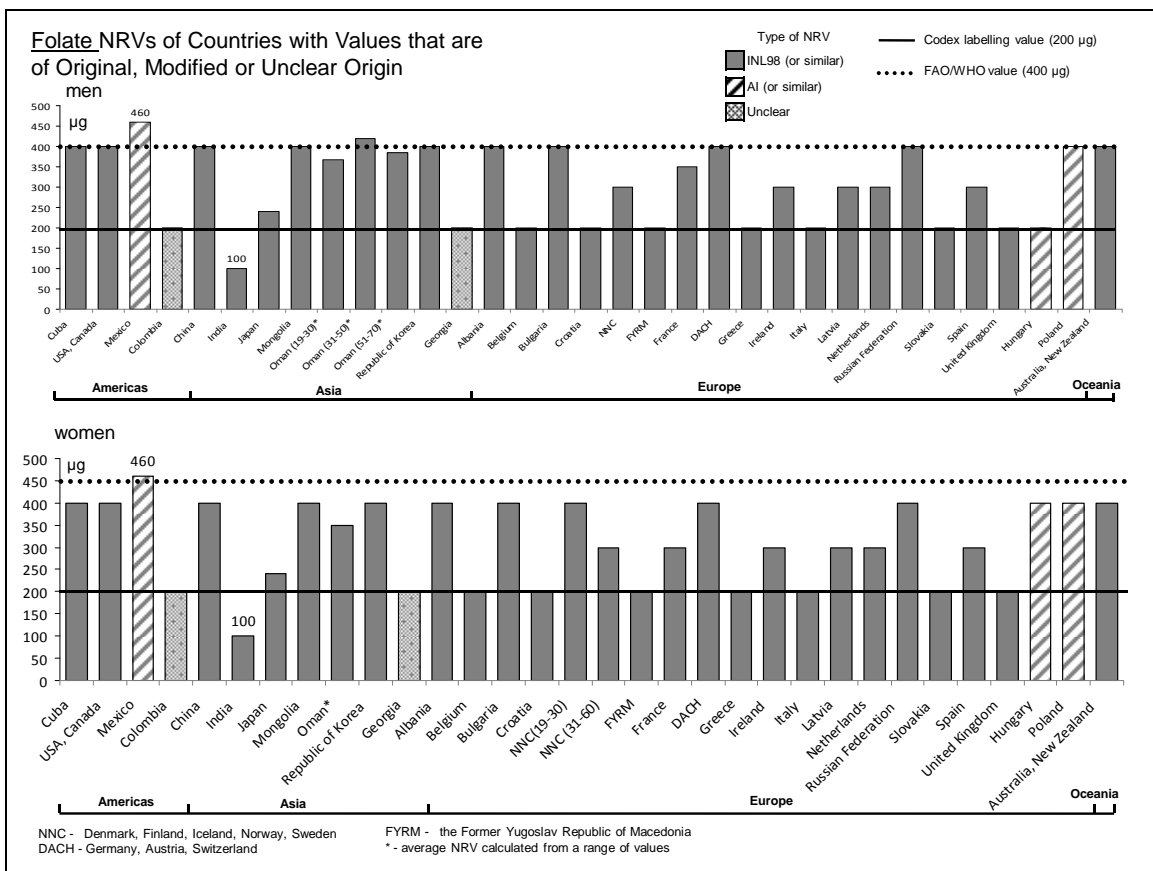
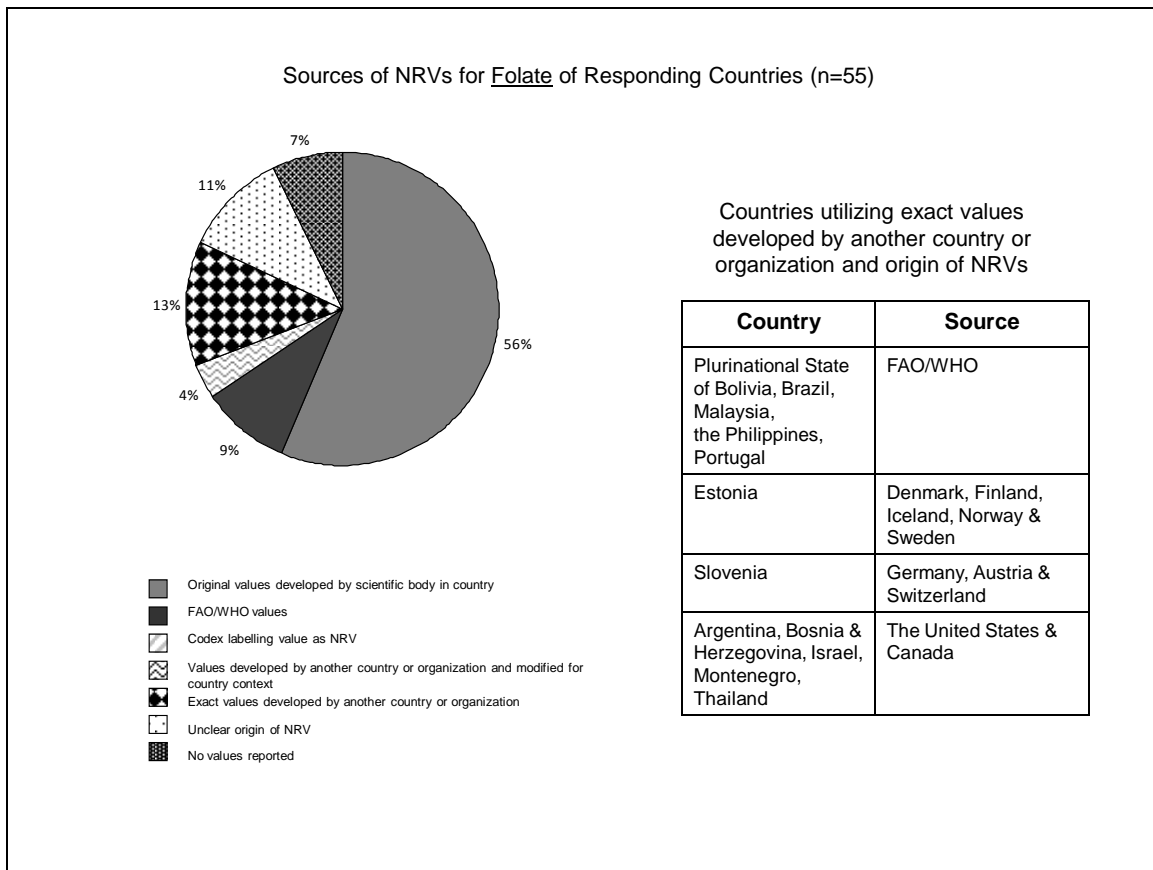


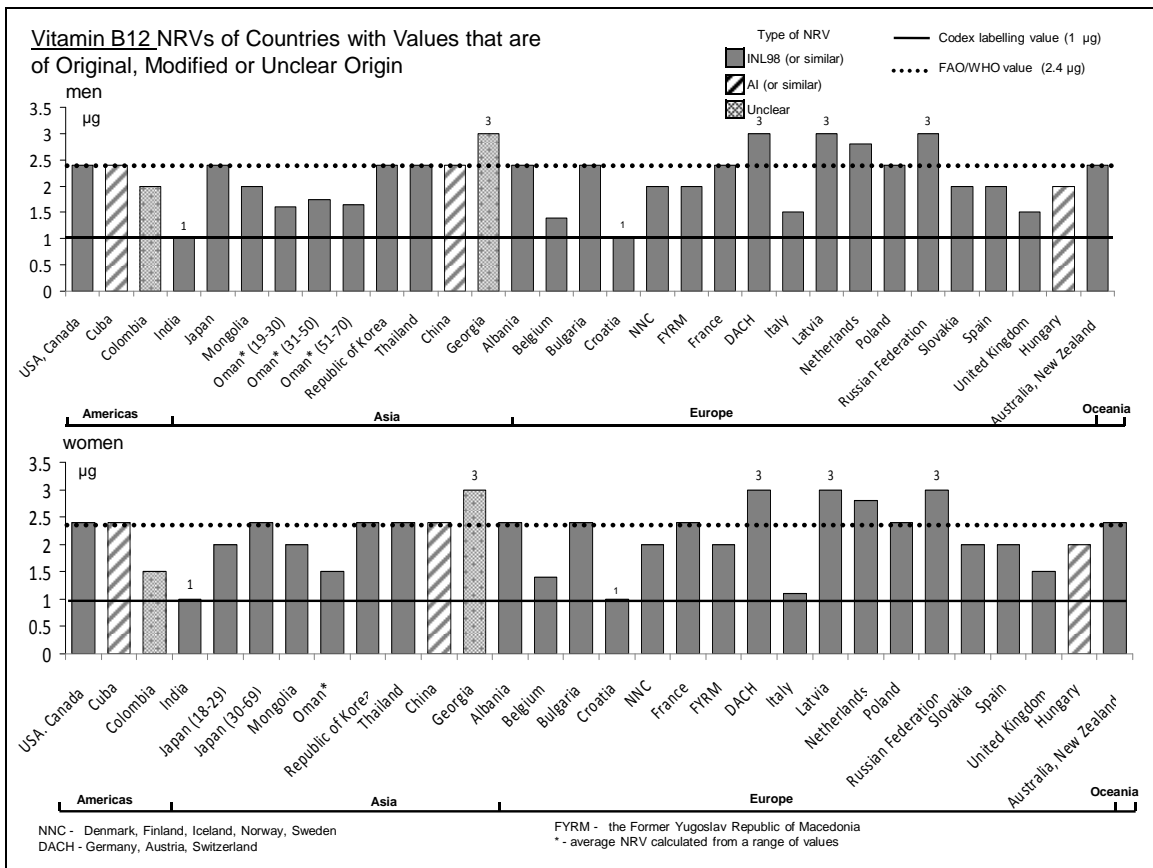
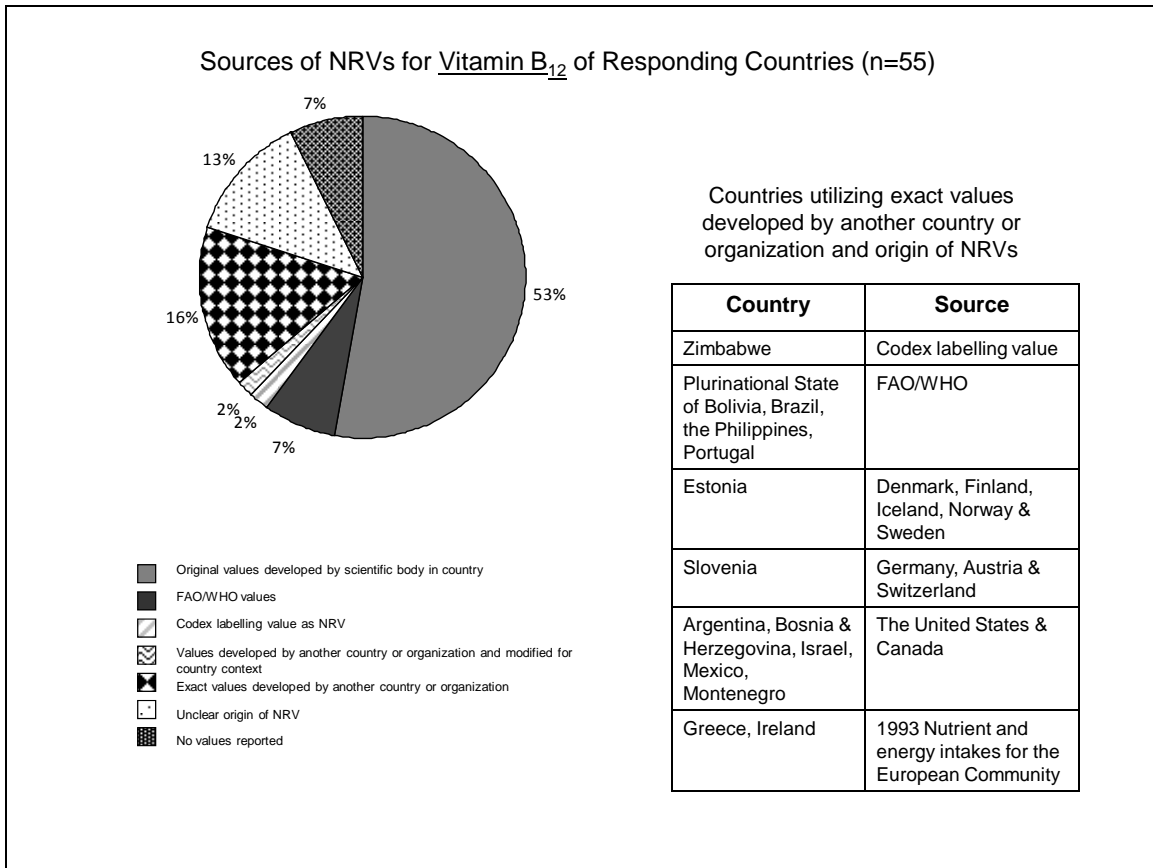


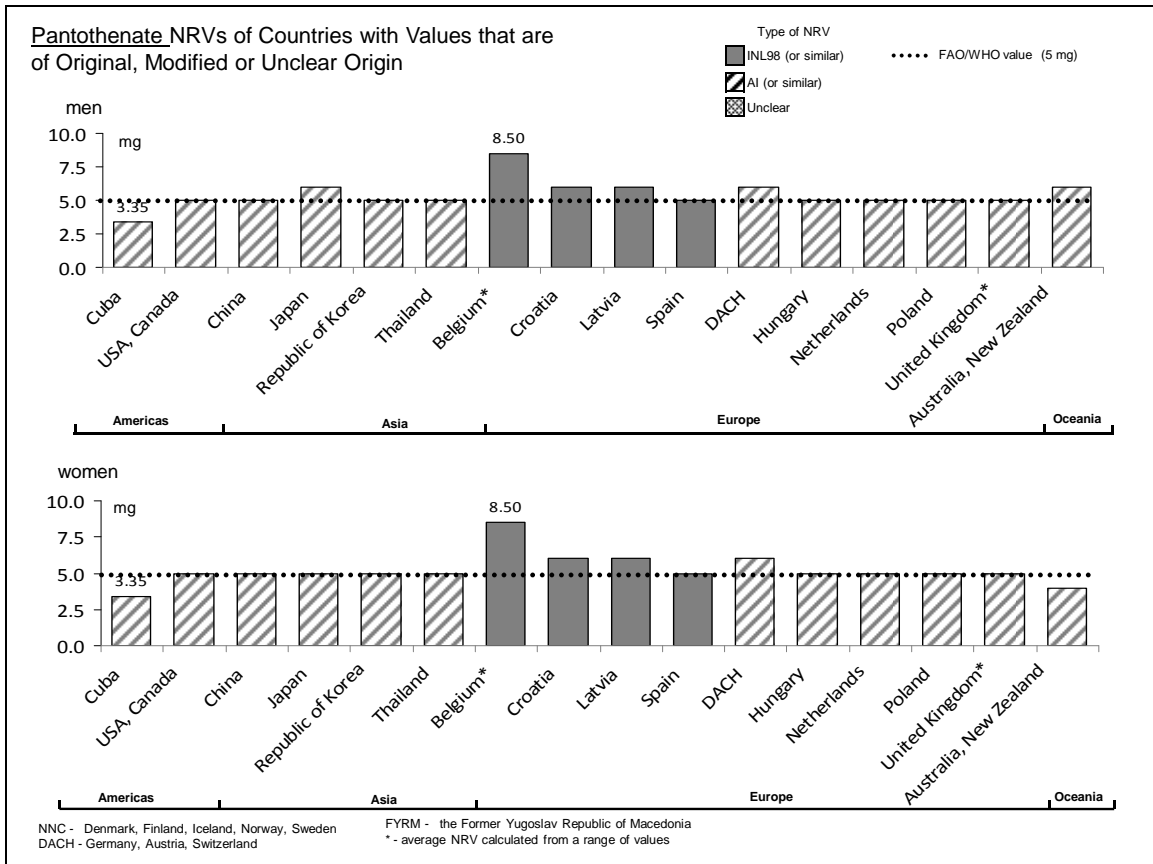
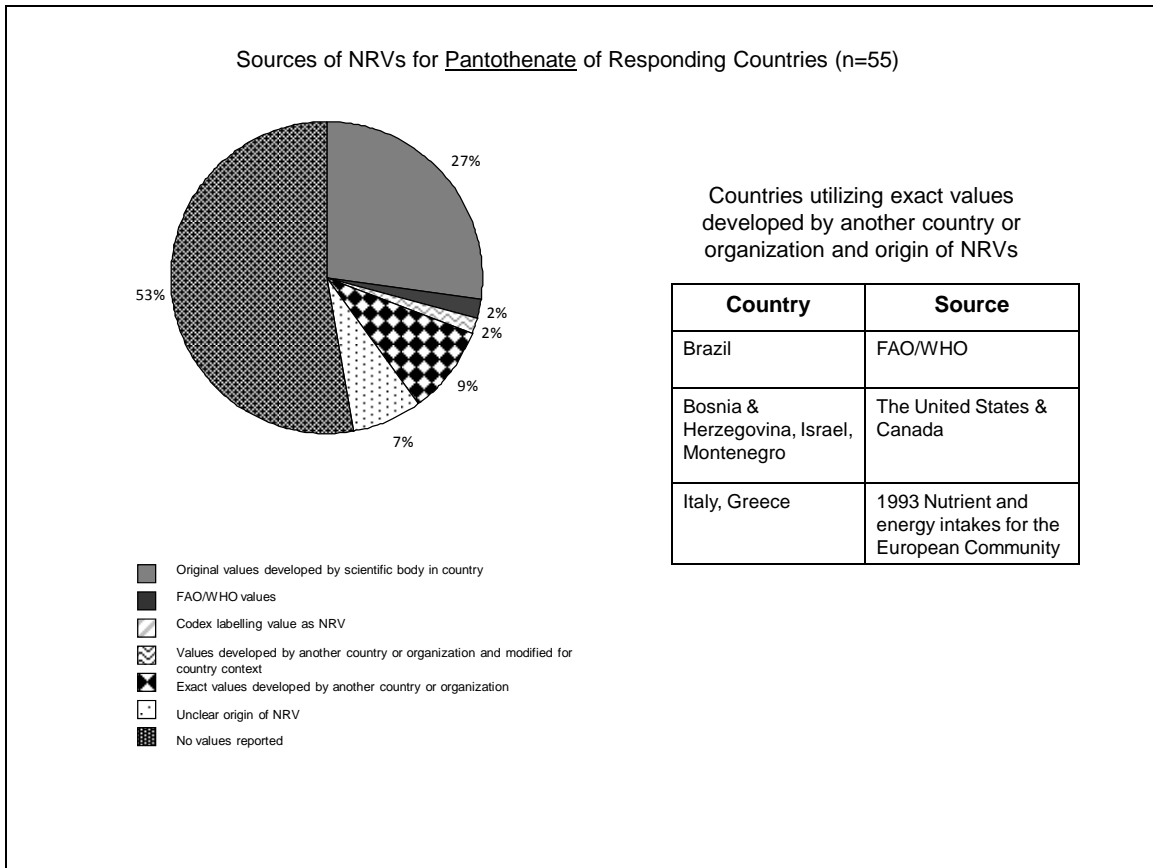


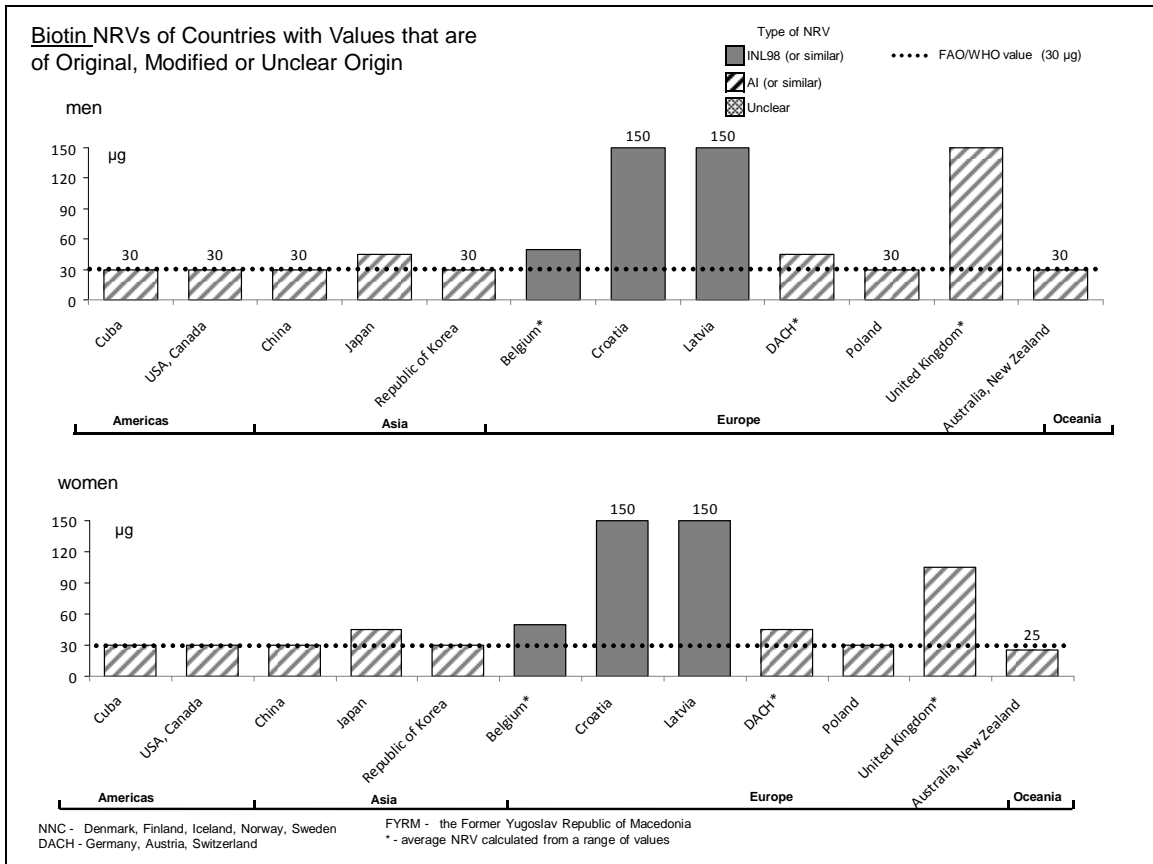
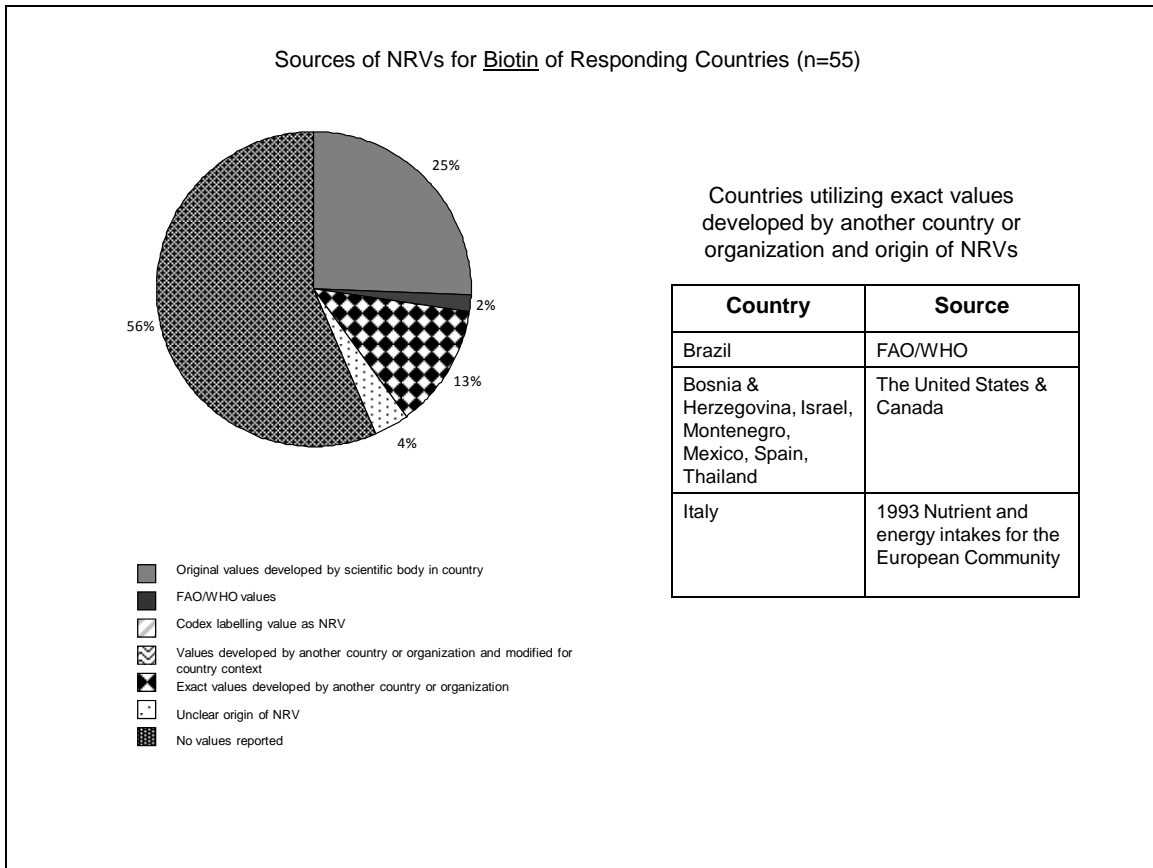


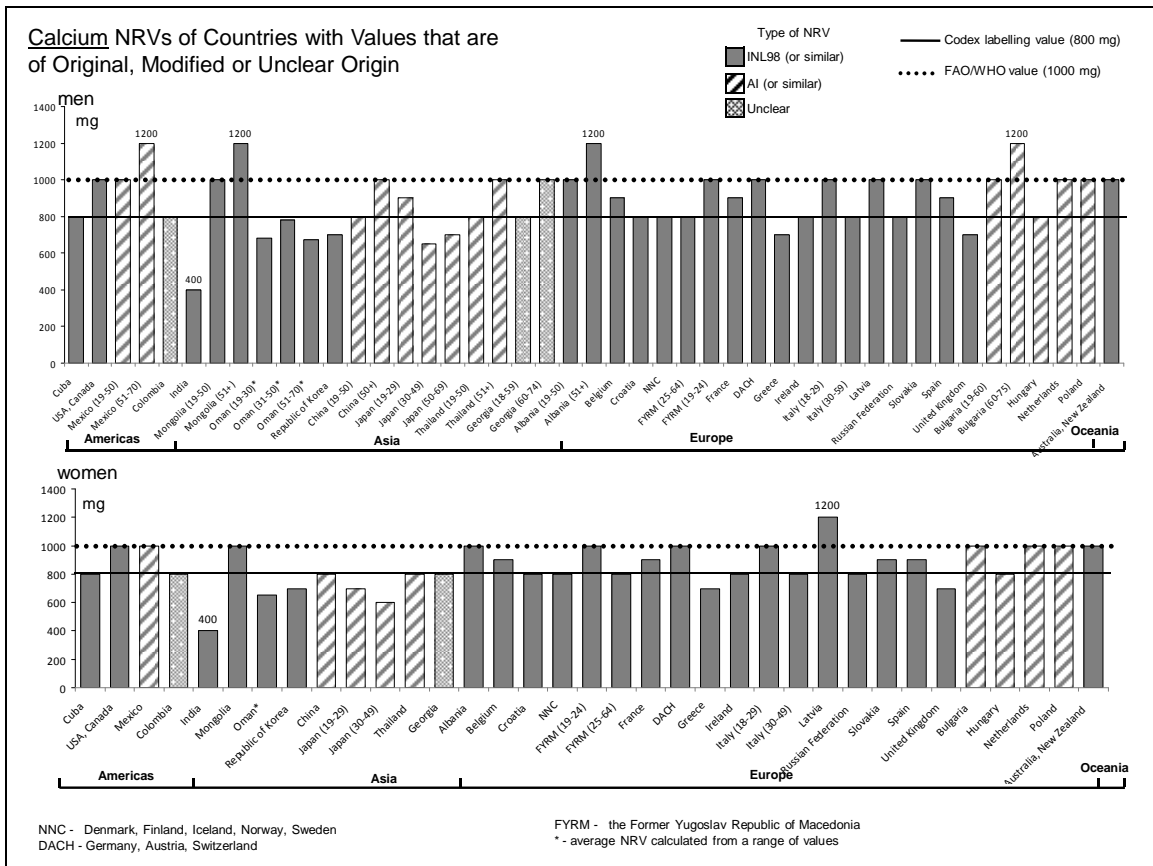
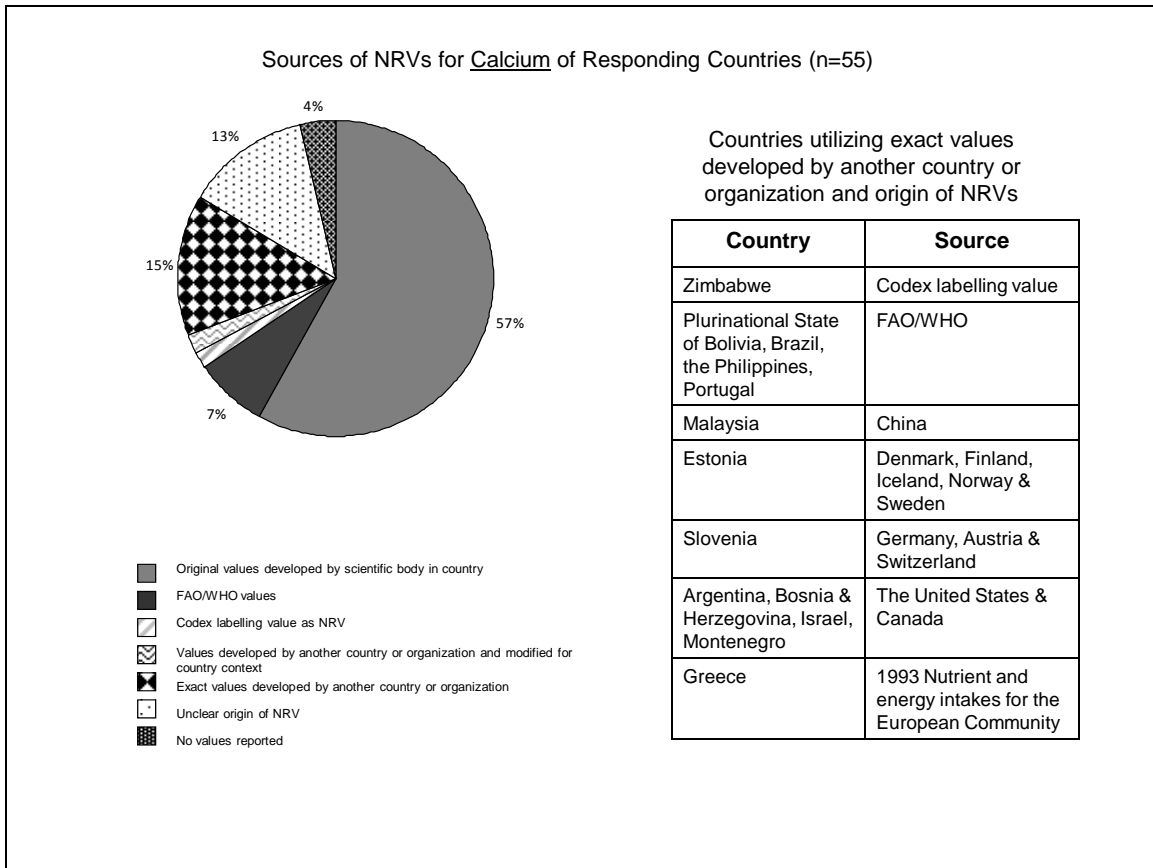


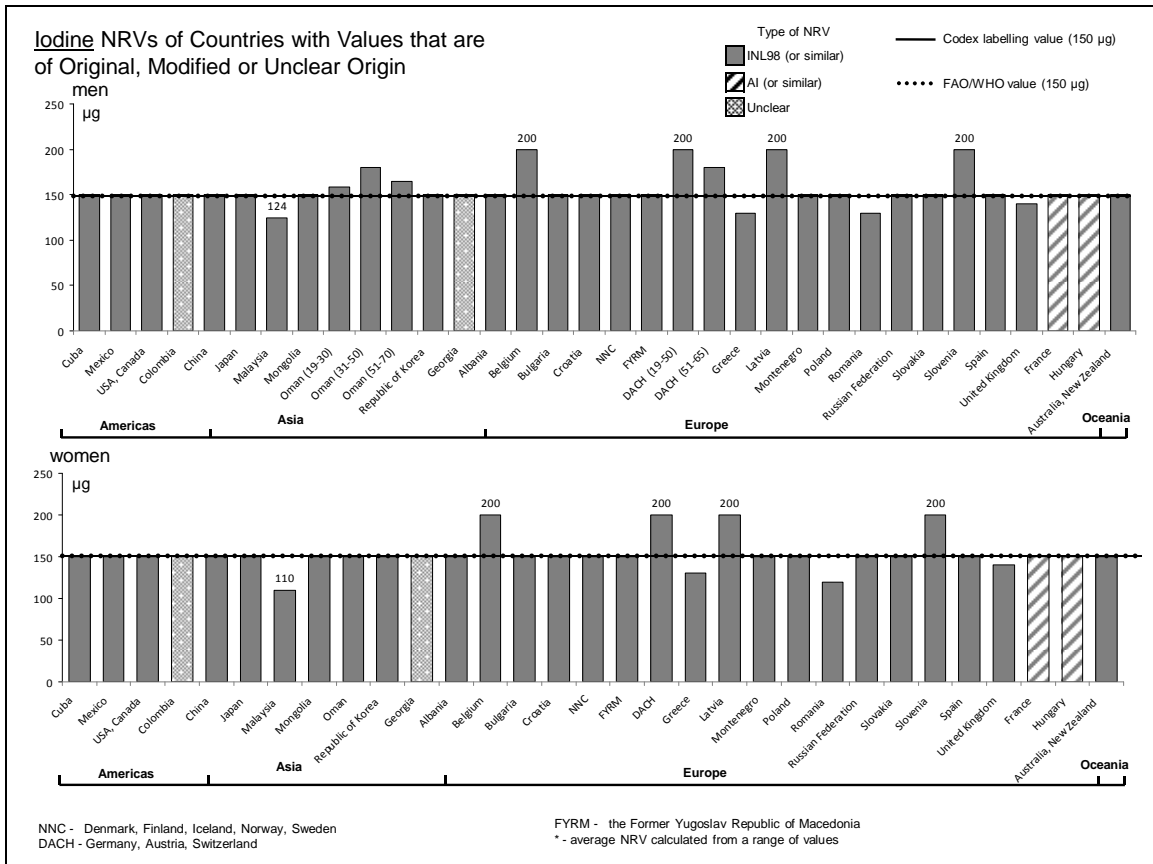
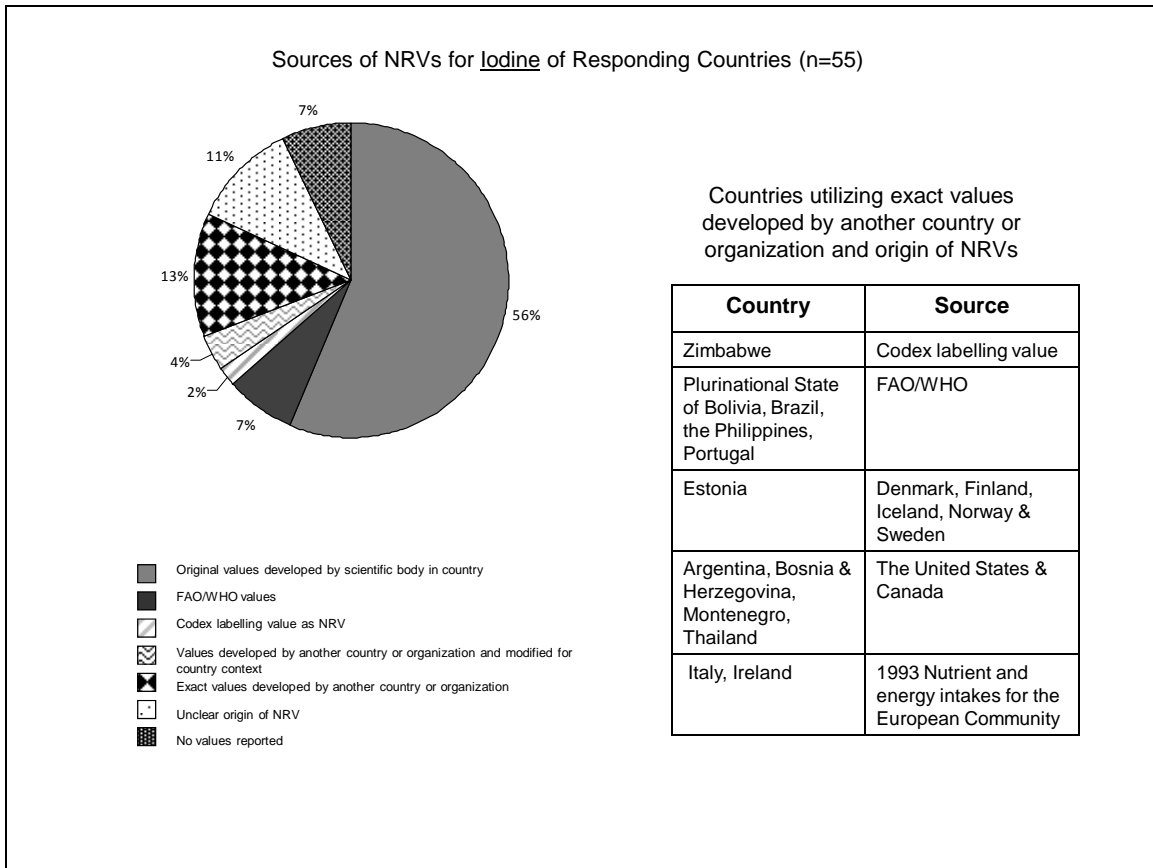


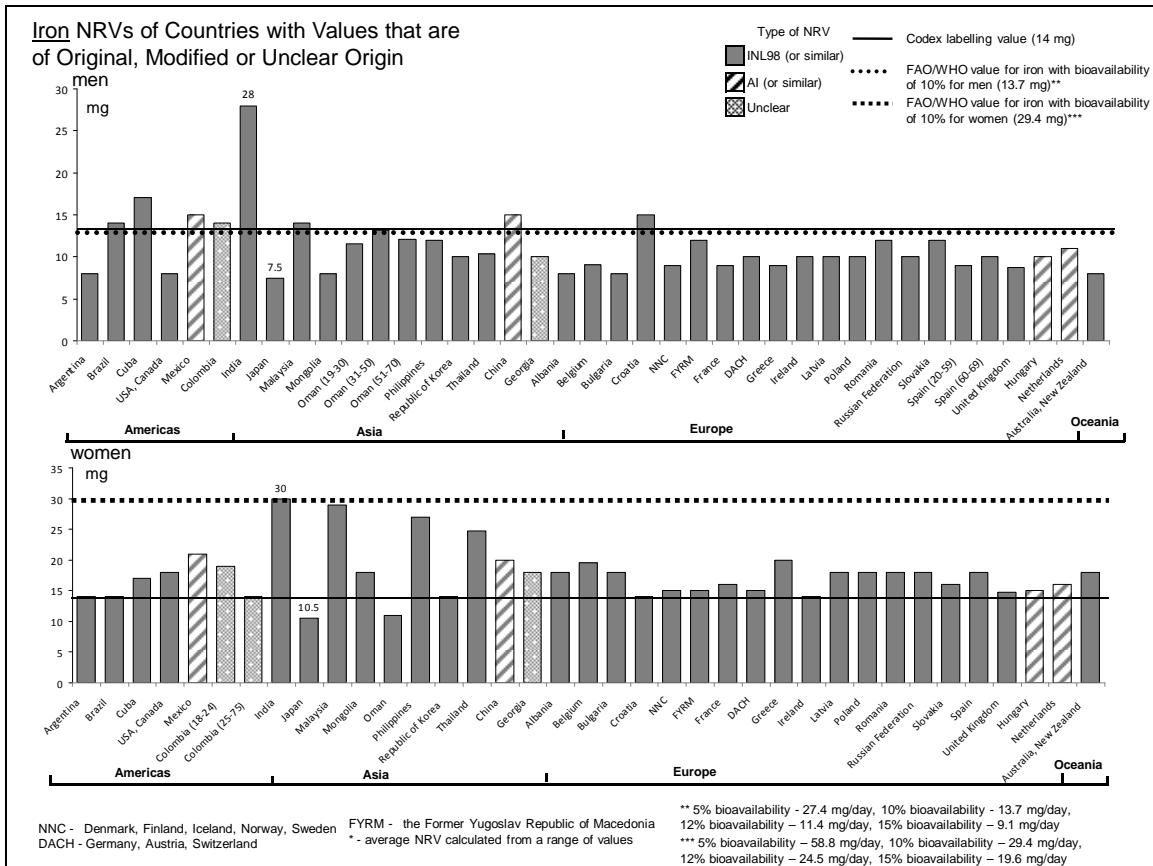
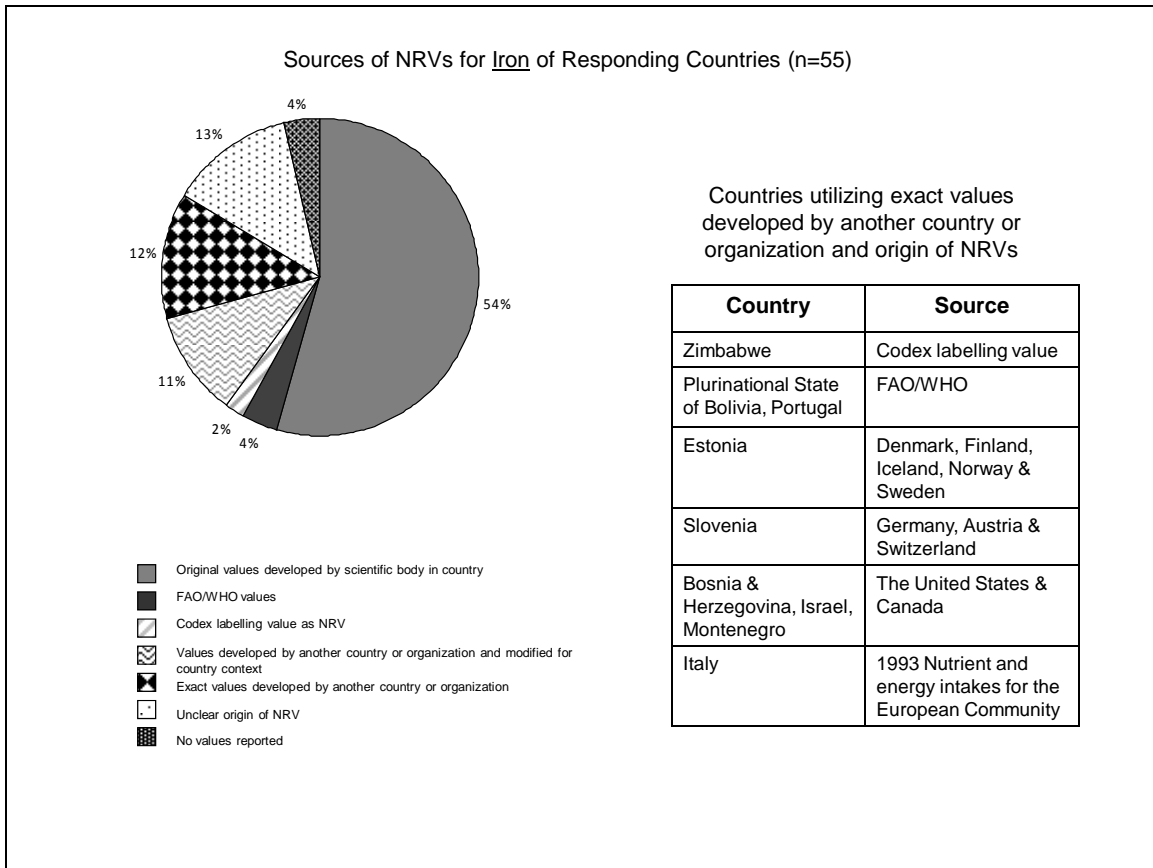


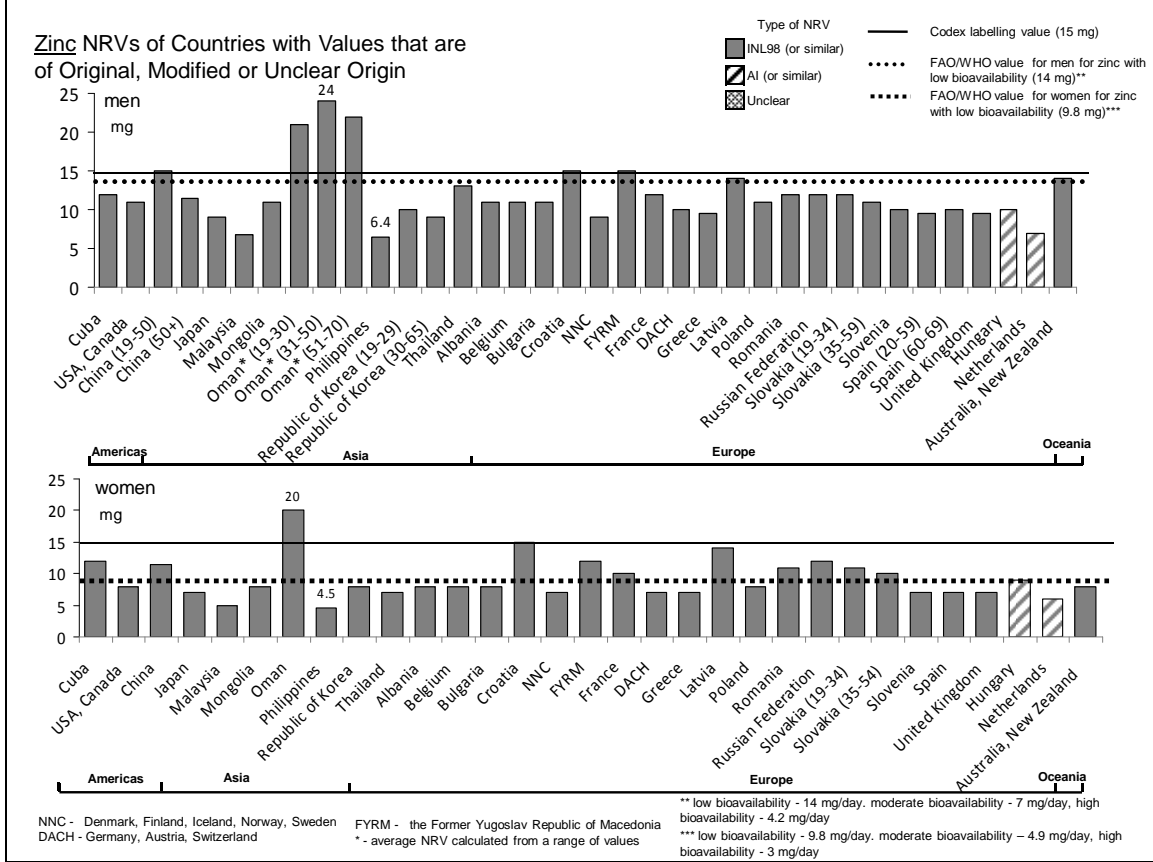
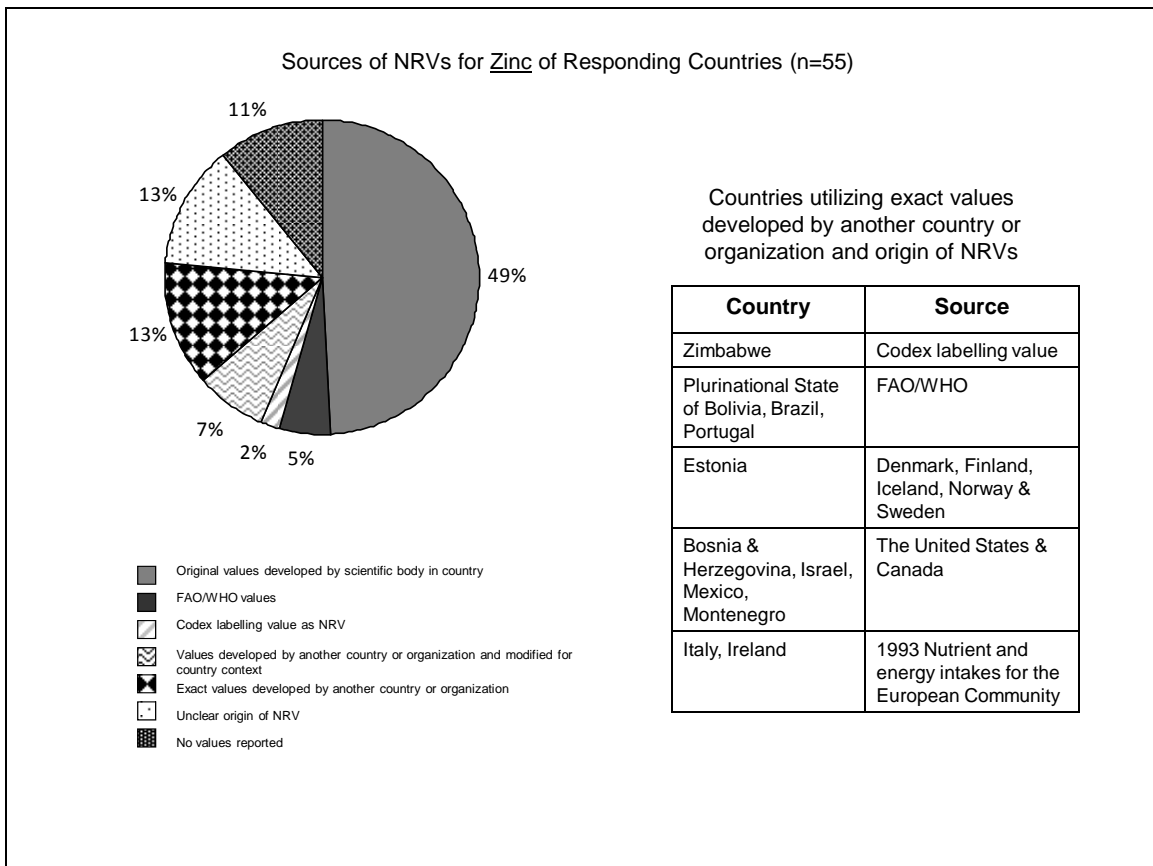












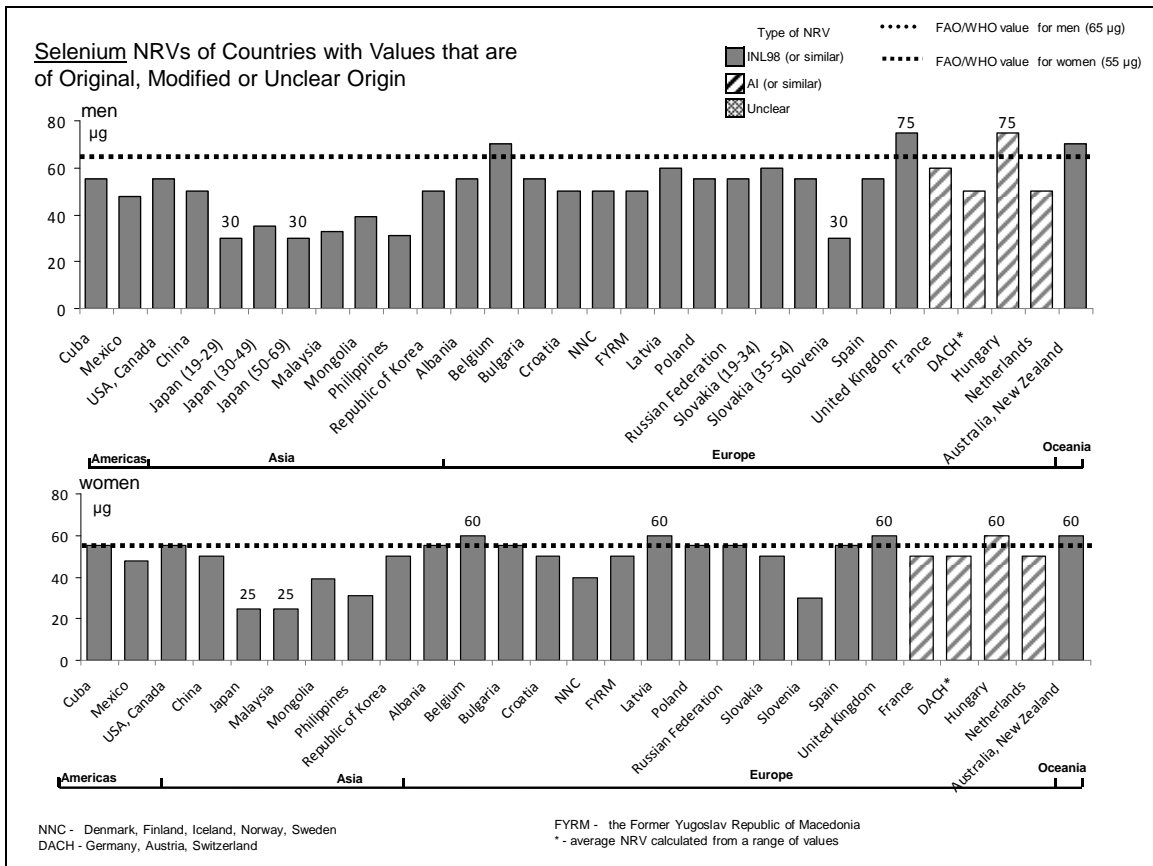
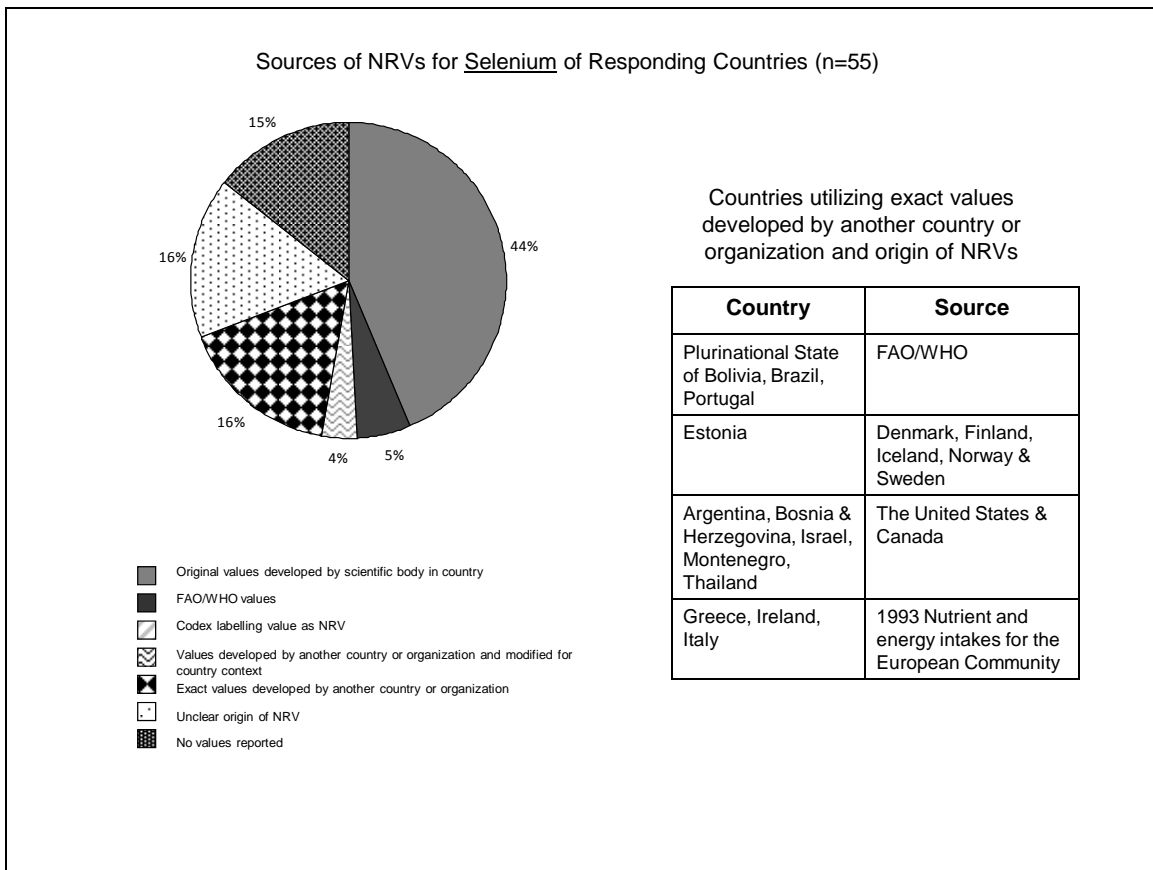
FAO/WHO

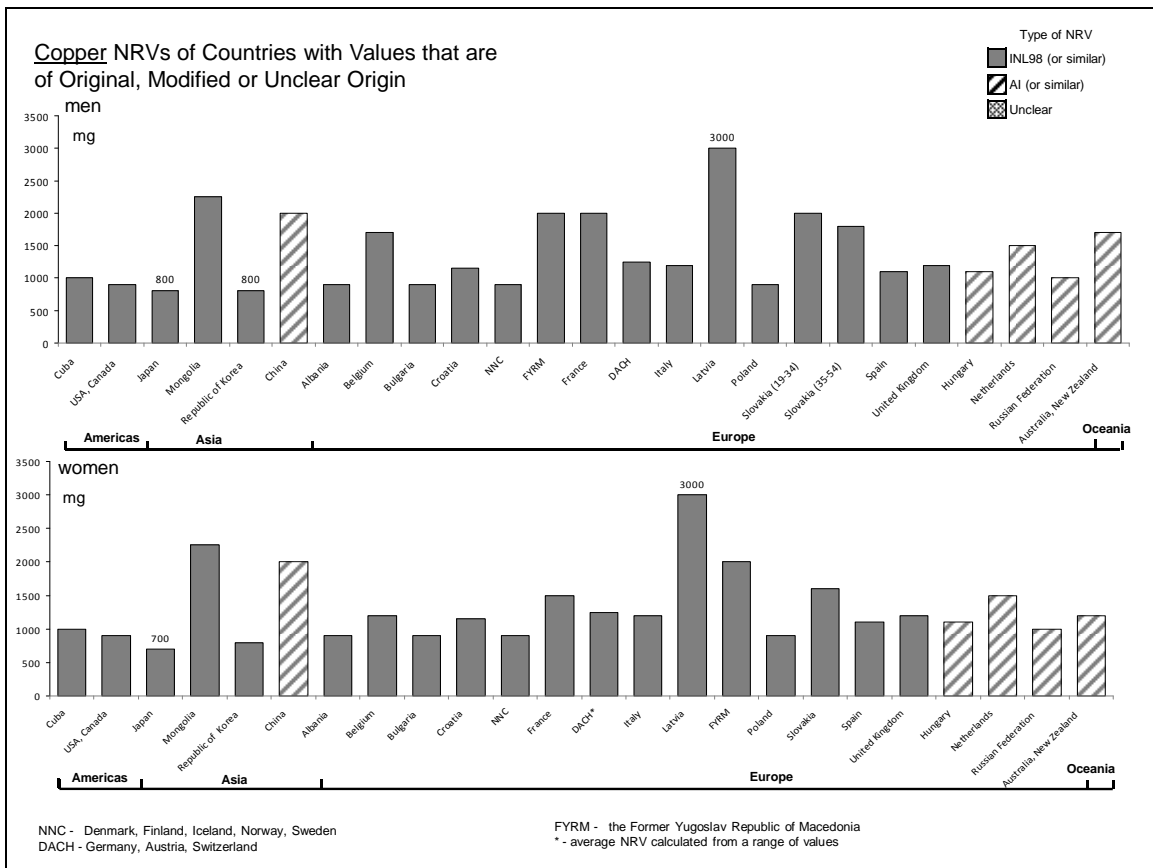
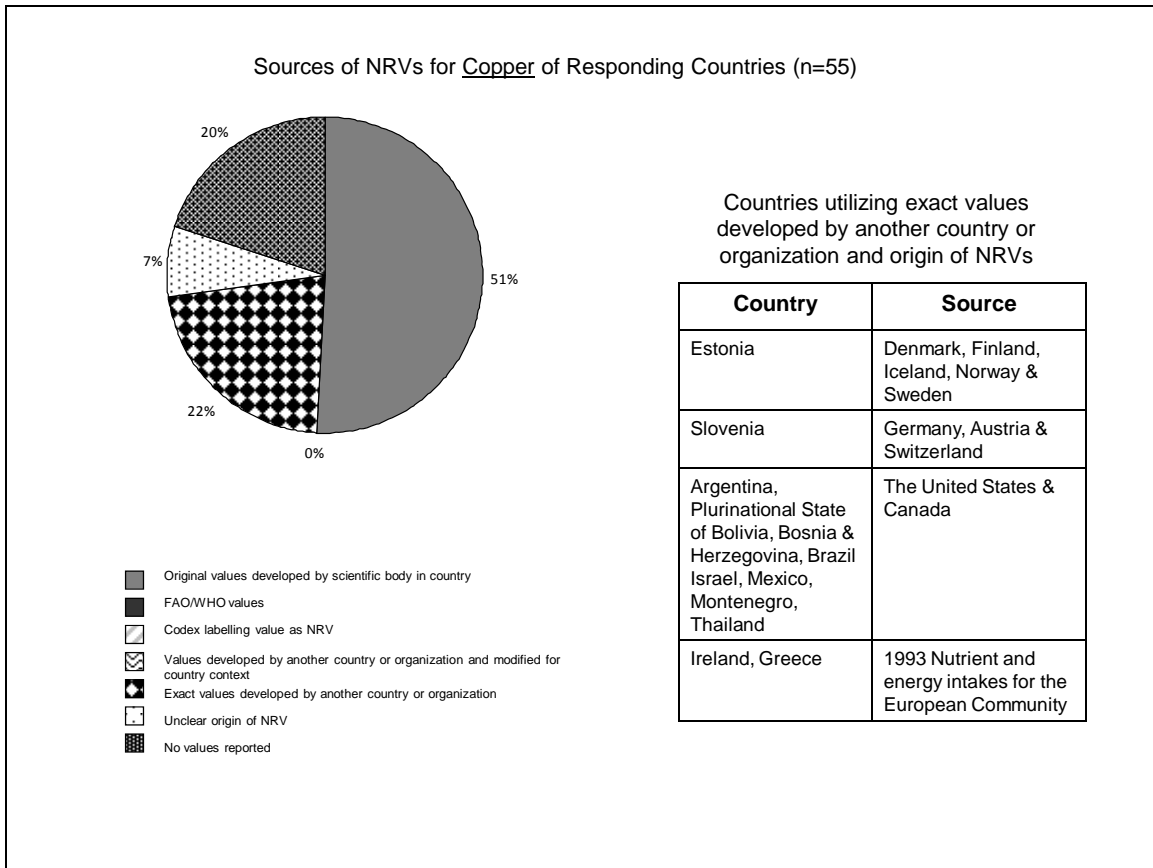
Men

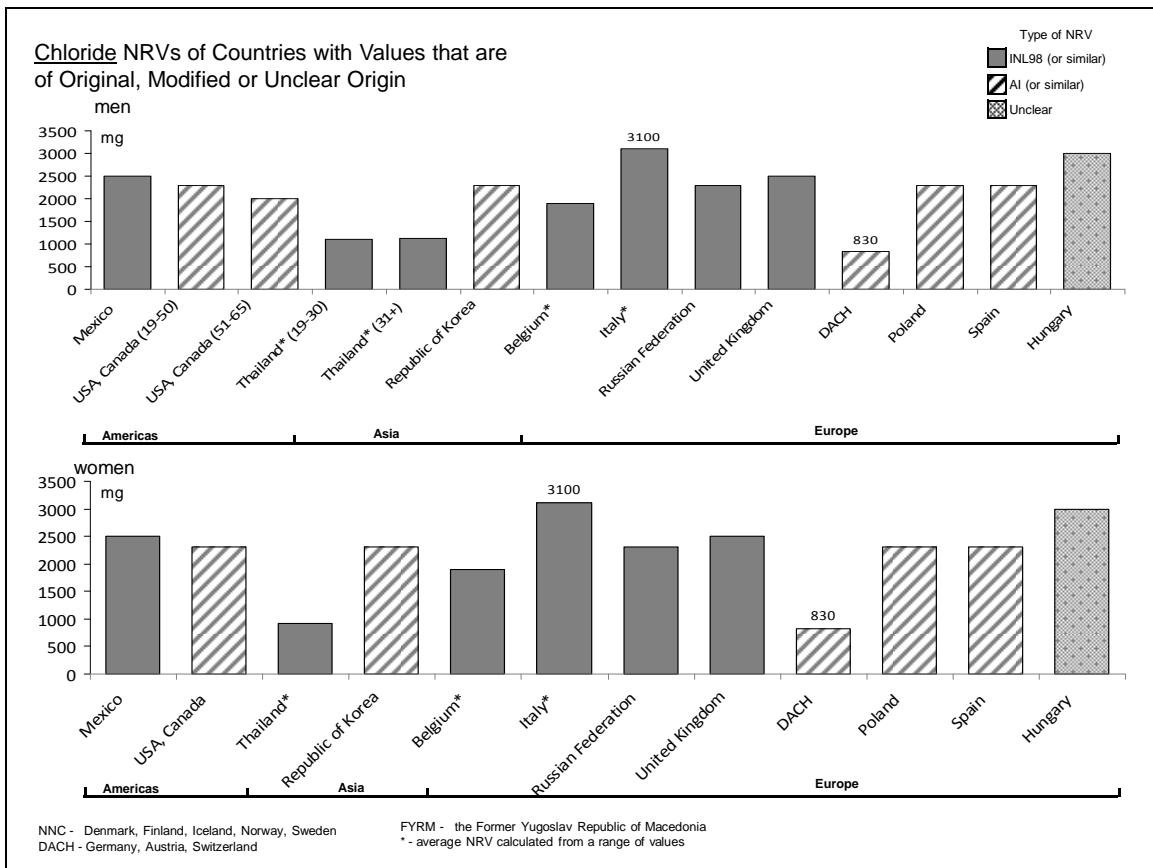
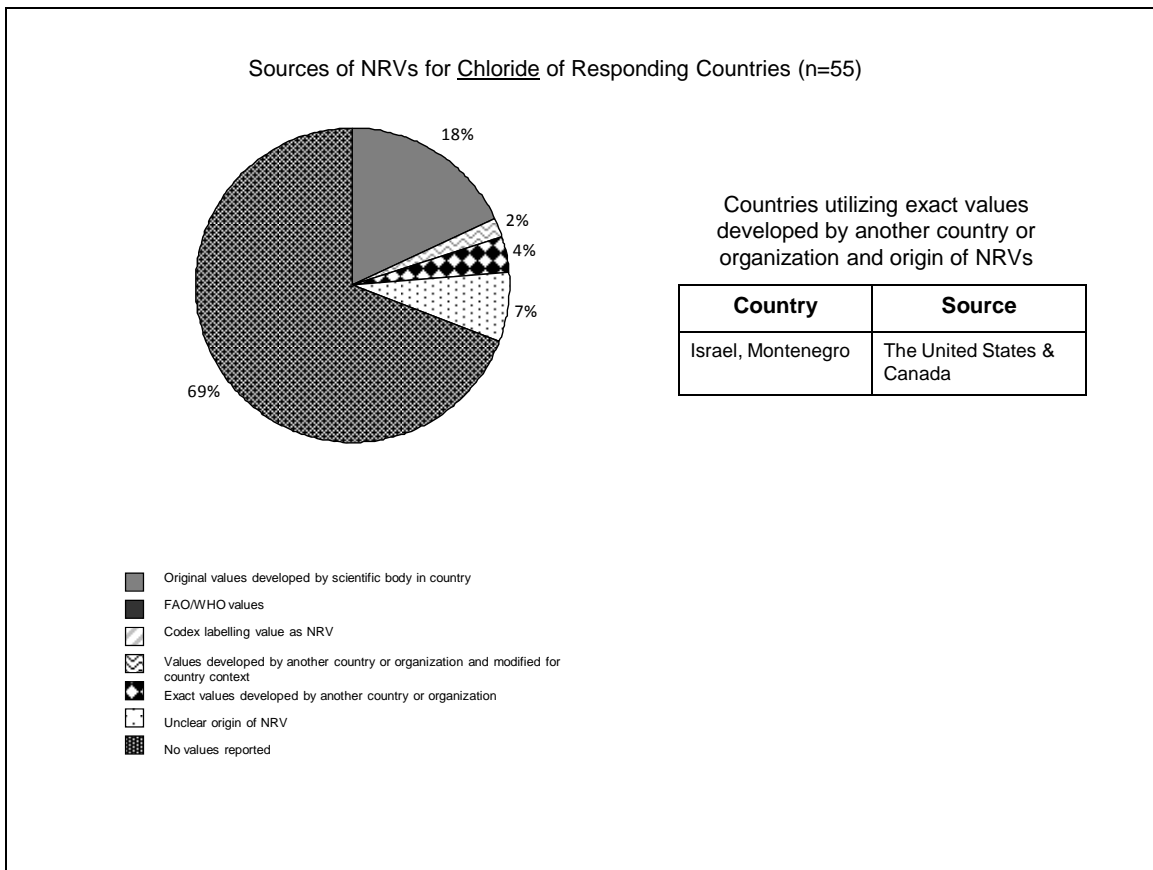
14 mg (low bioavailability), 7 mg (moderate bioavailability), 4.2 mg (high bioavailability)

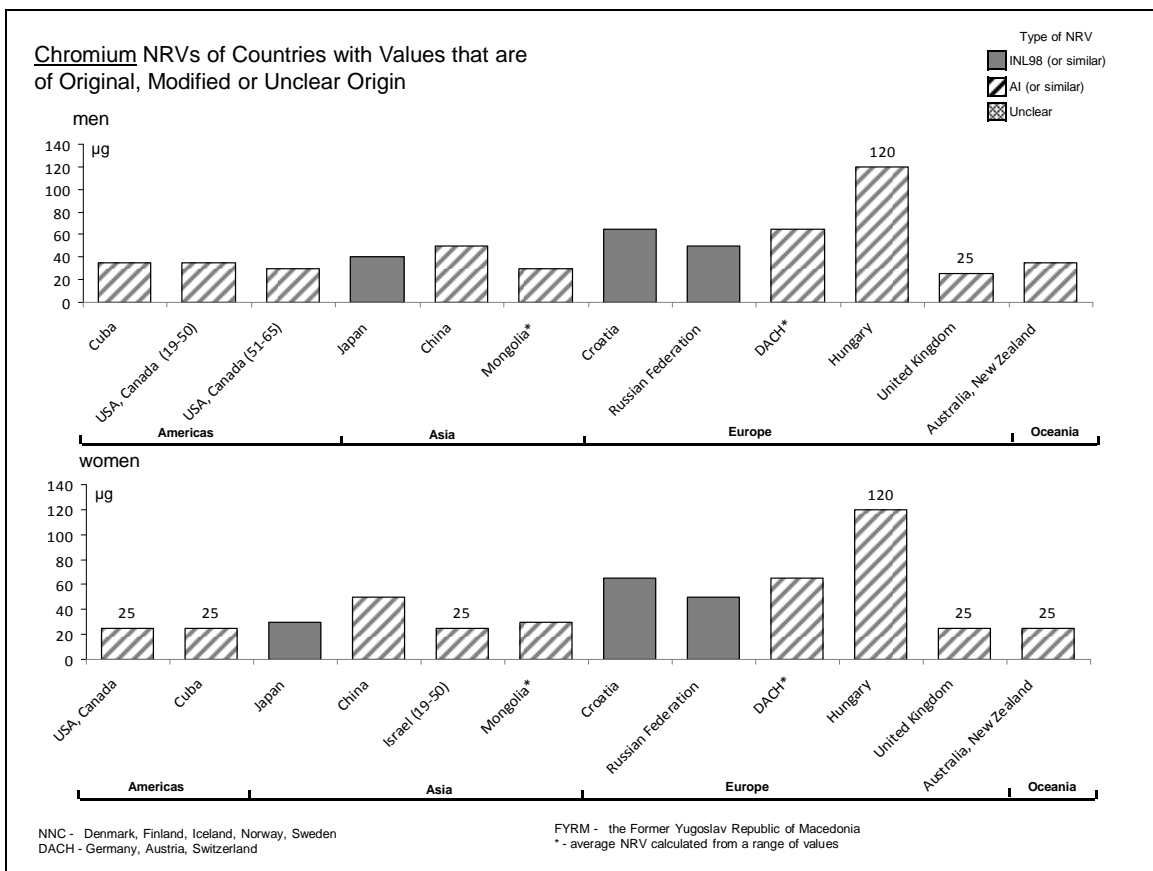
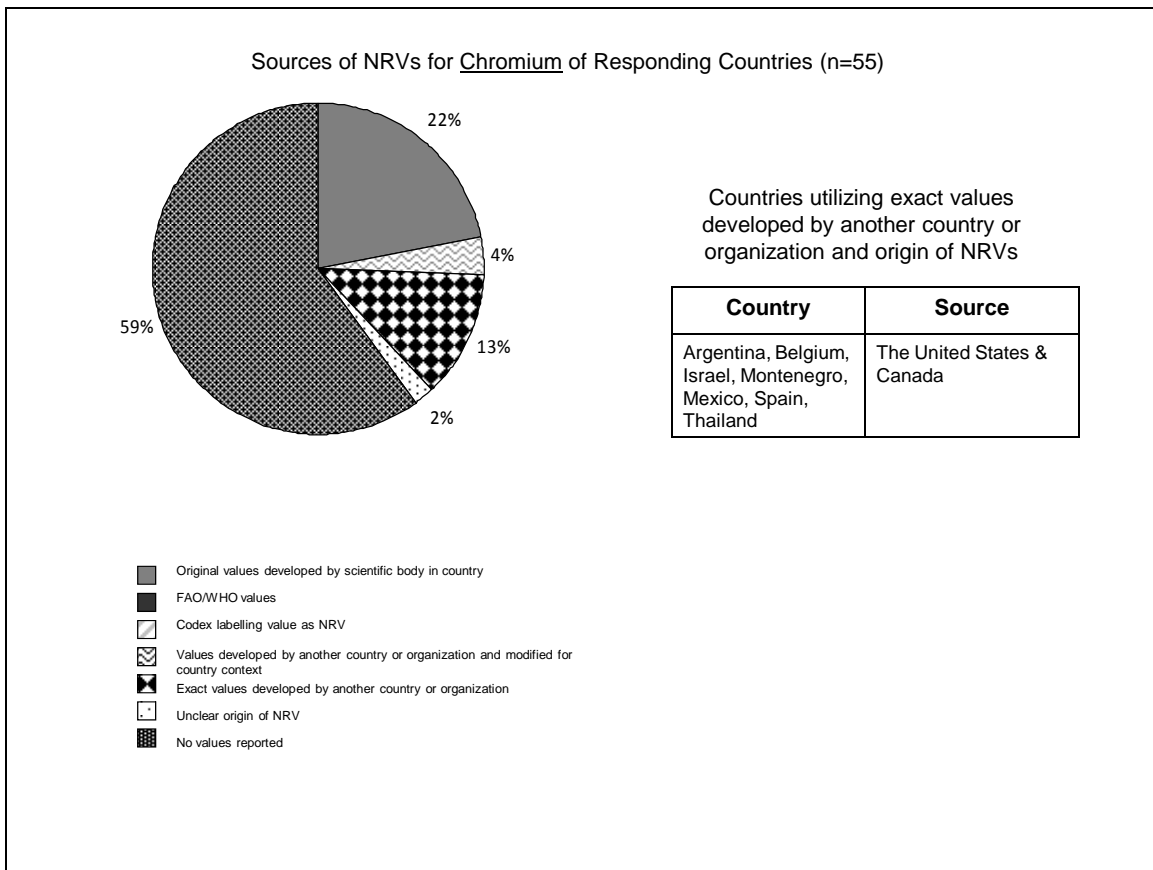
Women

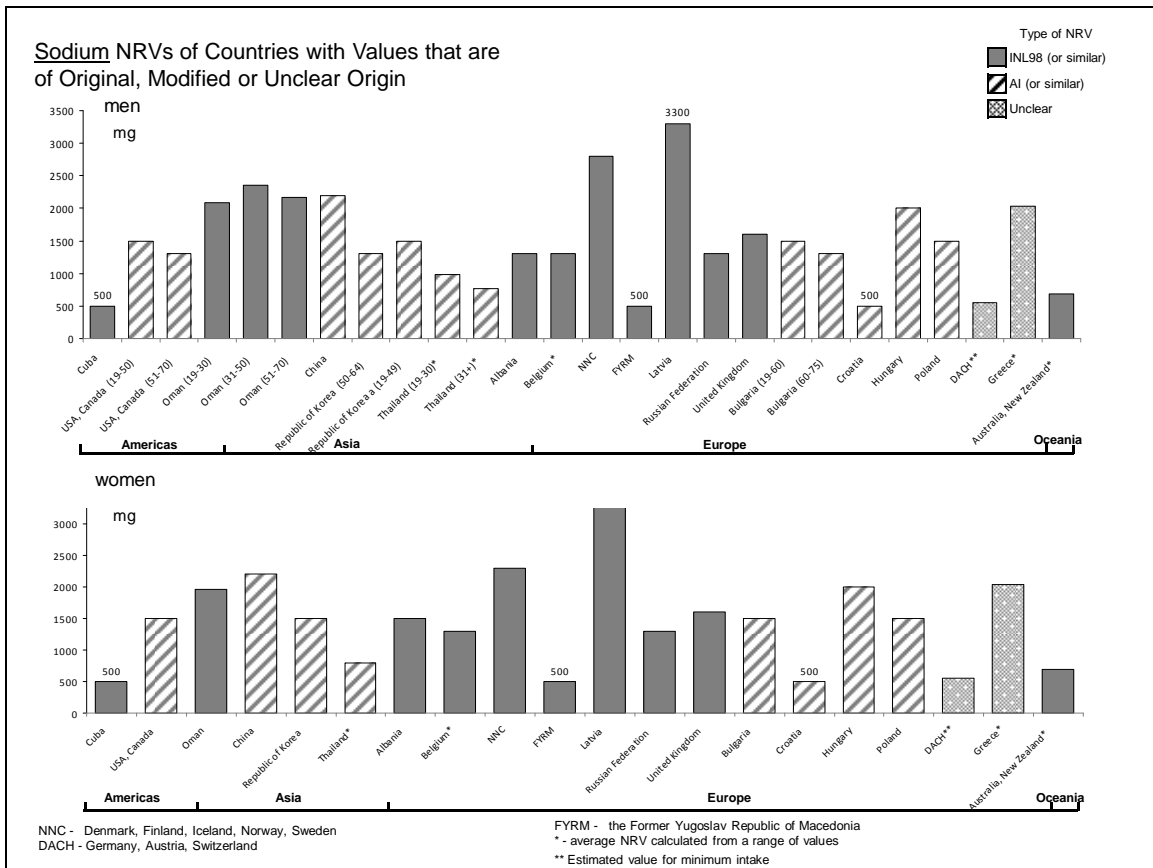
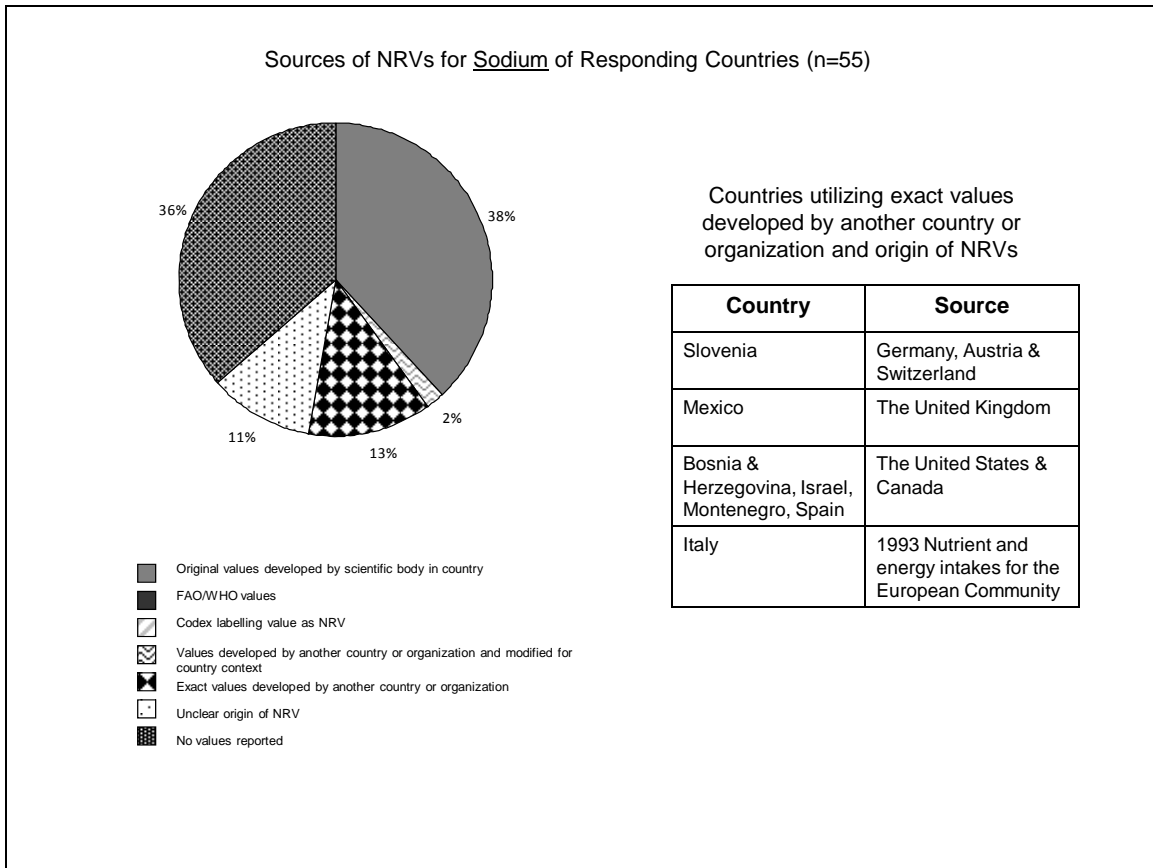
9.8 mg (low bioavailability), 4.9 mg (moderate bioavailability), 3 mg (high bioavailability)

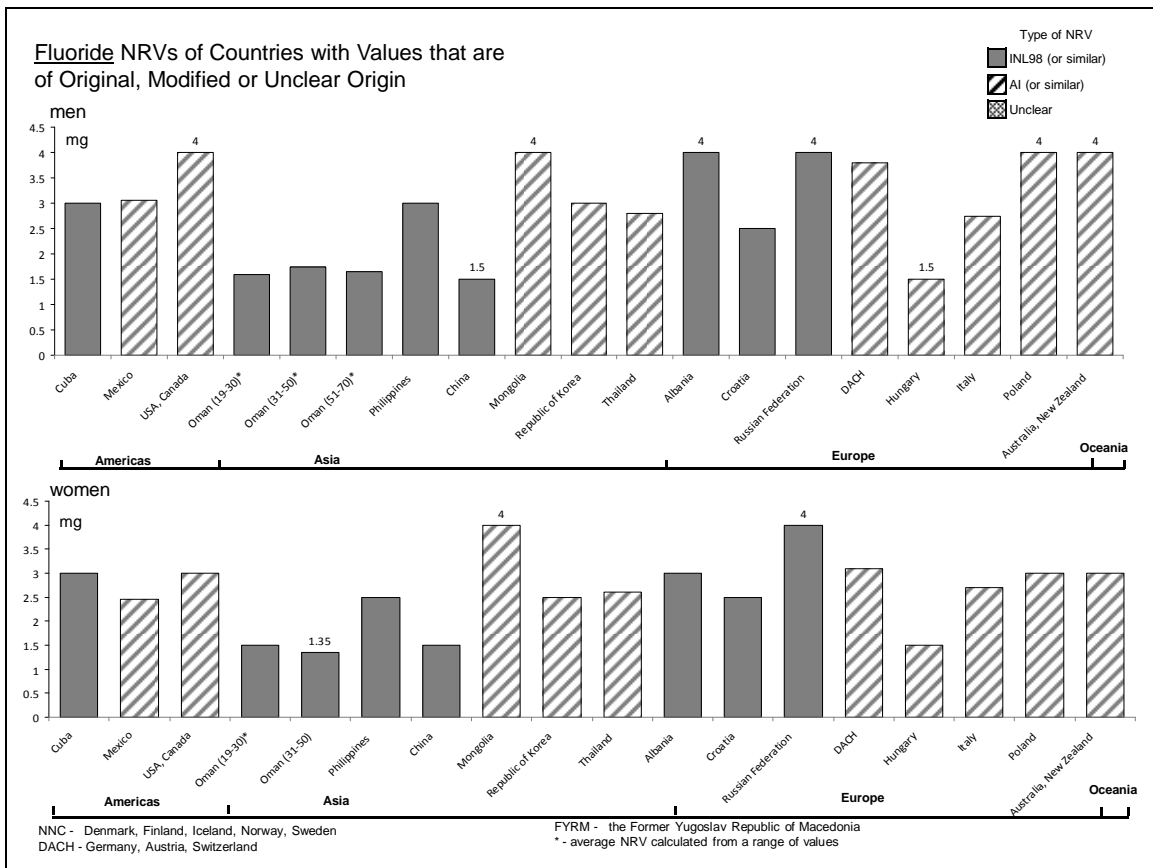
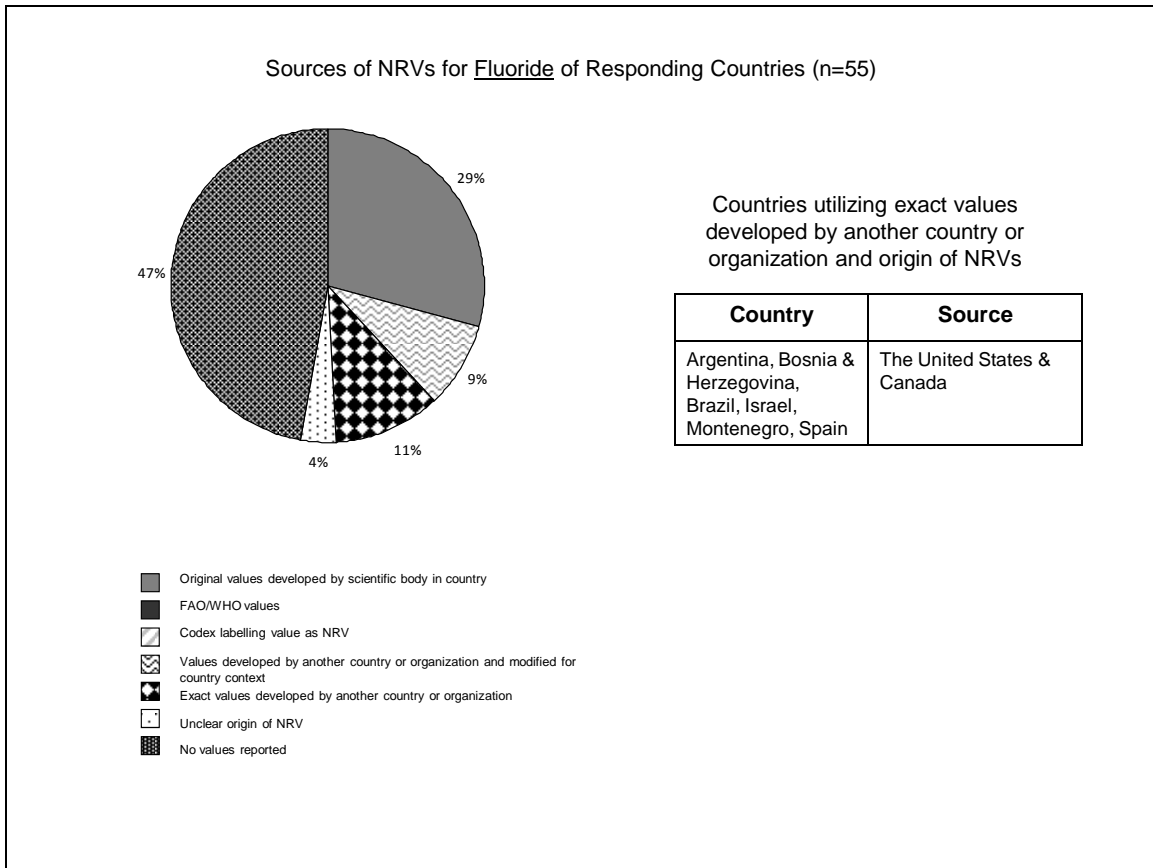


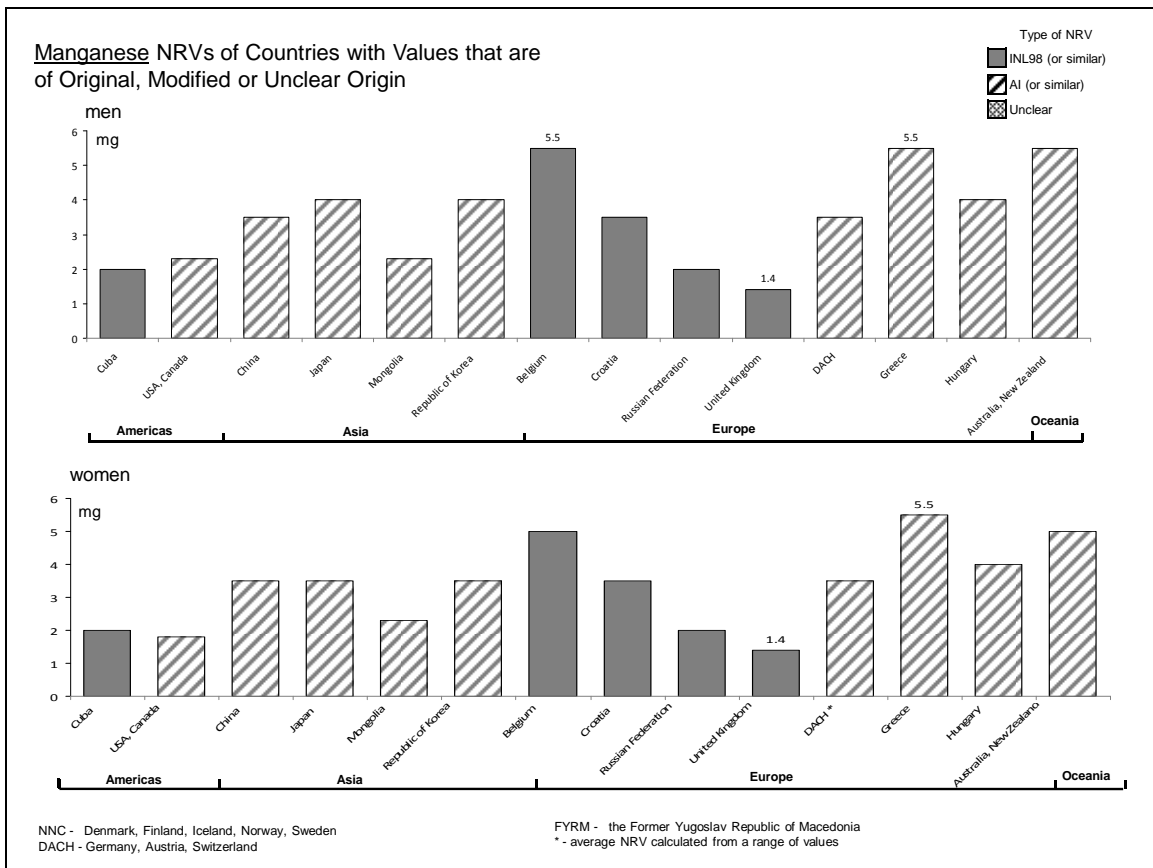
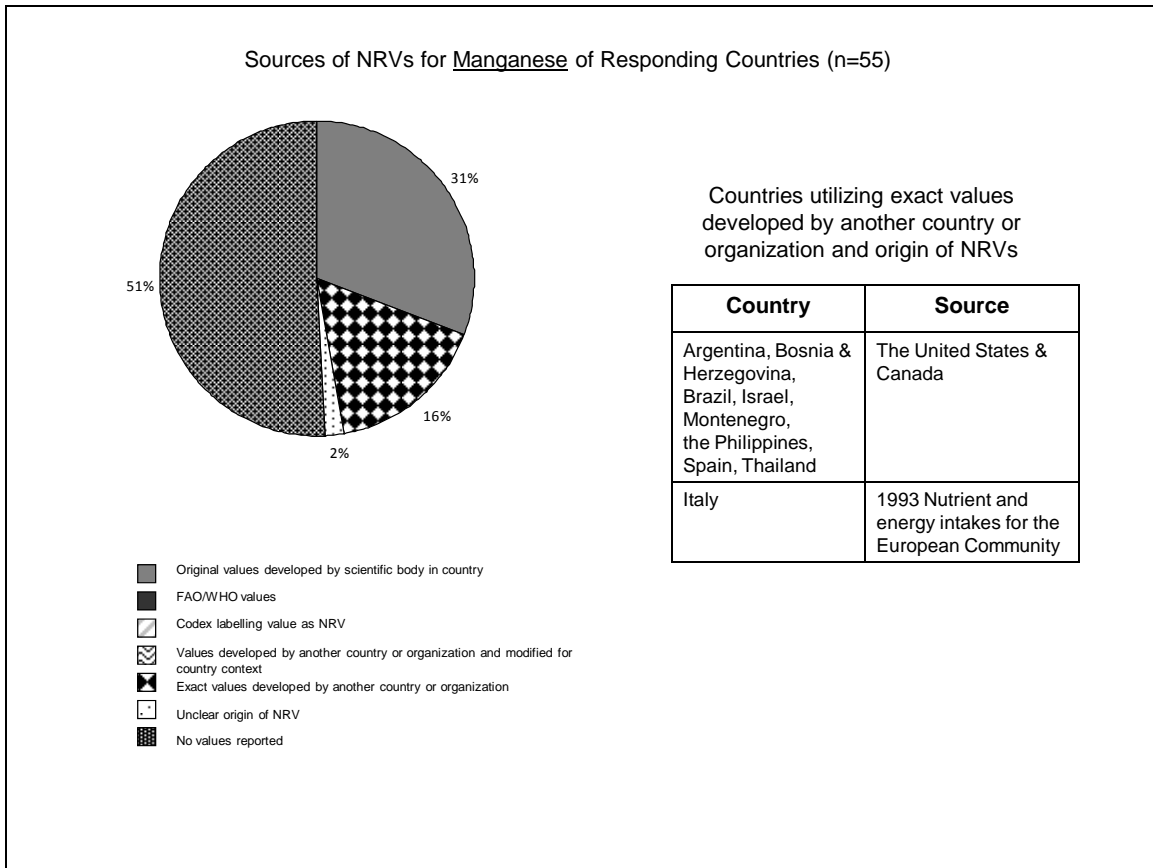




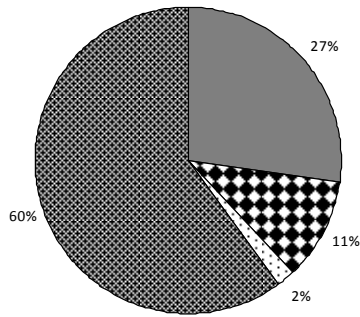








Sources of NRVs for Molybdenum of Responding Countries (n=55)

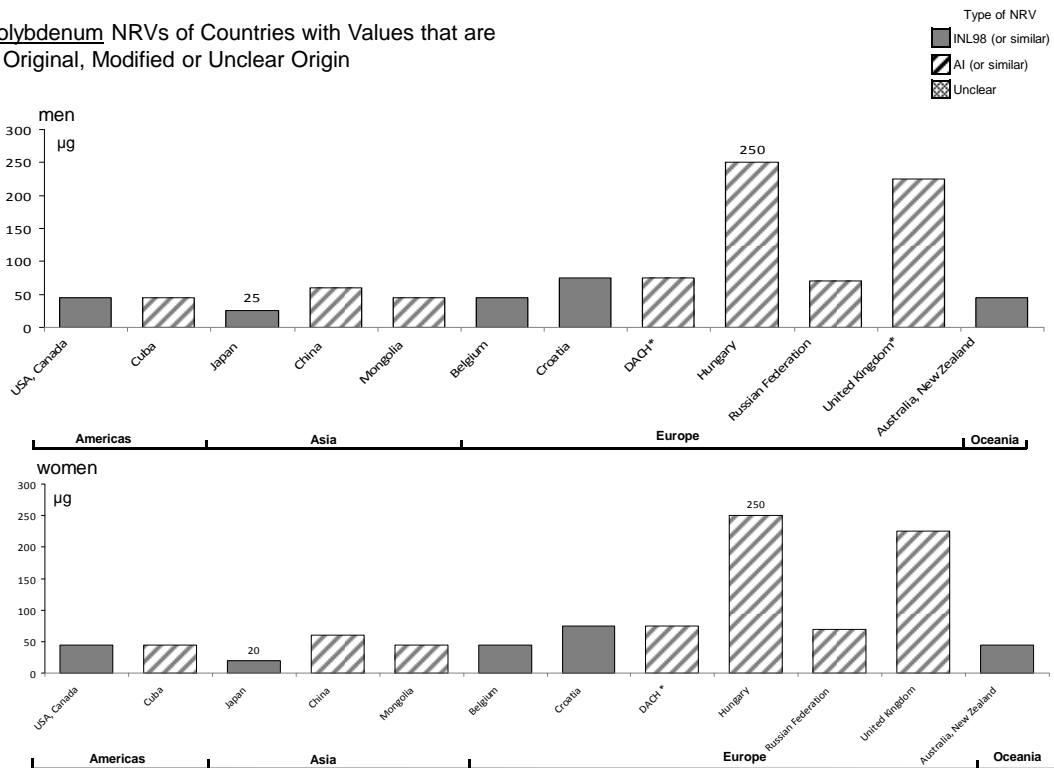


Countries utilizing exact values developed by another country or organization and origin of NRVs

| Country | Source |
|---|---|
| Brazil, Israel, Montenegro, Spain, Thailand | The United States & Canada |
| Italy | 1993 Nutrient and energy intakes for the European Community |

- Original values developed by scientific body in country
- FAO/WHO values
- Codex labelling value as NRV
- Values developed by another country or organization and modified for country context
- Exact values developed by another country or organization
- Unclear origin of NRV
- No values reported

Molybdenum NRVs of Countries with Values that are of Original, Modified or Unclear Origin



NNC - Denmark, Finland, Iceland, Norway, Sweden
DACH - Germany, Austria, Switzerland

FYRM - the Former Yugoslav Republic of Macedonia
* - average NRV calculated from a range of values

