International Peer Review of FSANZ Dietary Modelling Team Practices and Procedures

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Executive Summary

FSANZ is one of very few national regulatory agencies with a committed group of expert dietary modellers. Their participation in international programs, such as the JECFA, has been, and will continue to be solicited. As reported herein, the team's uses of data, assumptions, procedures, and models are all consistent with international best practice and meet or exceed expectations. The team's evaluations prepared for national risk and safety assessments are exemplary.

The FSANZ process is particularly efficient, in that all aspects of the risk assessment process are completed by employees at one location in Canberra ACT. Beyond convenience, this allows for the simple dissemination of information across both the management and technical segments of the risk analysis process.

The decisions of the Dietary Modelling Team, and indeed of the whole risk assessment structure, must be based on best available science. Changing priorities and availability of resources can often result in situations where their work is accomplished under pressure and with a high level of scrutiny by stakeholders, the public, and other government agencies. The data available to and the levels of expertise within the team are of sufficient quality to enable it to accomplish its tasks. FSANZ can be justifiably proud of the team's accomplishments and can look forward to considerable success from its continued support of their efforts.

Recommendations (summary)

1. The Dietary Modelling Team should consist of permanent appointees to ensure skill and knowledge retention and reduce the time spent on educating new temporary members.

2. It is desirable that food consumption data from nutrition surveys generate several days of food consumption data for respondents, to enable more refined chronic dietary exposure assessments to be carried out.

3. Efforts should be made to publish important dietary exposure assessments in the open literature thereby enhancing the scientific credibility of FSANZ's dietary modelling capability.

4. The transparency and presentation of the dietary exposure assessments and data in written reports should be further enhanced.

5. FSANZ should ensure that dietary exposure assessments are 'fit for purpose' and are appropriate for available resources. Utilization of the full DIAMOND tool is not necessary in many instances.

6. FSANZ should continue to seek alternative sources of food consumption data for validation of its dietary exposure assessment outcomes.

7. FSANZ should continue to support the use and development of the DIAMOND software package, including relevant documentation.

8. FSANZ should continue to encourage the participation of its Dietary Modelling Team members in international fora, such as JECFA.

9. FSANZ should continue its practice of having important documents and dietary exposure assessments peer-reviewed by outside experts.

10. FSANZ should investigate the feasibility of developing capabilities to undertake dietary exposures assessments for flavours and packaging contact materials.

11. Consideration should be given to how dietary exposure results derived using 24-hour recall food consumption data should be reported.

Additional discussion of these recommendations are detailed at the end of this review.

Introduction

I was invited by Food Standards Australia New Zealand (FSANZ) to make a presentation at the 2006 inaugural Science Network Workshop on Dietary Modelling, held in Canberra ACT, 28-29 September. I presented an overview of the history and place of dietary modelling in the international regulation and evaluation of food ingredients and contaminants. This workshop was intended as an opportunity for FSANZ stakeholders, including State regulators and academics, to examine in detail the science basis for FSANZ decision-making concerning dietary modelling. My participation in the workshop, and in an extended visit with the staff at FSANZ from 26 Sept to 2 Oct, enabled me to provide an international peer-review of the procedures used at FSANZ, including data sources, software, default assumptions, and the output of their dietary modelling evaluations.

My background is as an organic chemist, having received a Ph.D. from Columbia University (New York, USA) in 1982. After two post-doctoral positions, the second specializing in carbohydrate chemistry and taste perception, I became a chemistry technical reviewer at the US Food and Drug Administration (FDA) in 1988. A primary responsibility in this position was the estimation of intake[1] for additives as part of their premarket safety evaluation. In subsequent years, my expertise in exposure assessment has become recognized internationally through publications and my participation in the Joint FAO/WHO[2] Expert Committee on Food Additives (JECFA) and other international projects involving dietary modelling.

Scope

The aim of the review was to assess FSANZ dietary modelling procedures in relation to international best practice.

The scope was to review FSANZ dietary modelling procedures for food chemicals including nutrients, food additives, contaminants, agricultural and veterinary chemicals, novel foods or ingredients and other food chemicals, not including microbiological assessments.

The terms of reference for the review are at Appendix 1.

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[1] Throughout this review, the terms "intake estimation", "estimation of intake", "exposure assessment", "exposure estimation", "exposure evaluation", and "dietary modelling" may be used interchangeably.

[2] Food and Agriculture Organization/World Health Organization of the United Nations

Process and tasks

Process

As a WHO participant at the JECFA I have had the opportunity since 1998 to observe some of the dietary modelling procedures used at FSANZ (previously known as the Australia New Zealand Food Authority, ANZFA) and presented as part of JECFA evaluations of food ingredients or contaminants. Additionally, I had provided a peer-review of the 21st Australian Total Diet Study in early 2006 which included food preservatives (sulphites, benzoates and sorbates). Prior to arriving in Canberra on 25 Sept 2006, I examined publications and reports published by FSANZ on various aspects of dietary modelling. This included an overview of the Dietary Modelling of Nutrition Data (DIAMOND) software package used by the Dietary Modelling Team, a report from a 2005 FSANZ workshop on dietary modelling and risk characterization, a methodological investigation report from an FSANZ contract statistician, as well as monographs drafted for the JECFA by FSANZ scientists.

During 26-27 Sept 2006 I met with FSANZ Chief Scientist to discuss the role of peer-review in FSANZ overall Science Strategy 2006-9, which was officially launched at the Science Network Workshop on the 28 Sept. The scope of the peer-review was discussed, as were the specifics of FSANZ participation in international dietary modelling projects. Additionally, I had discussions with the CEO of FSANZ and the Chairman of the FSANZ board. These discussions served to emphasize the commitment of FSANZ to providing the best scientific advice to stakeholders and to keeping current with international activities in dietary modelling and broader risk analysis procedures.

During these two days I met with the Section Manager of the Modelling, Evaluation, and Surveillance Section (MESS), with whom I have had numerous previous interactions, both as participants in the Intake Group at JECFA and as members of international workshops and expert consultations on exposure assessment organized by FAO/WHO. These discussions served to deepen my understanding of the procedures used by FSANZ in using dietary modelling for risk assessments.

My host at FSANZ is the leader of the Dietary Modelling Team. Over the course of my visit to FSANZ we had numerous discussions concerning the data, assumptions, and techniques used by the team in its evaluations. I was introduced to the four members of the team, with whom I discussed their overall approach to dietary modelling and some of the specific projects that are currently being completed within the team.

On 26 Sept, I made a presentation to FSANZ staff on the workings of the Office of Food Additive Safety, in the Center for Food Safety and Applied Nutrition at the US FDA. This presentation afforded the opportunity to meet with FSANZ stakeholders, including the food industry, health professionals and other Australian Government departments, to discuss their questions concerning FSANZ dietary modelling practices, specifically in the context of how the same activities are done at FDA.

On 28-29 Sept, I attended and made a presentation to the 2006 Science Network Dietary modelling Workshop, held in Canberra ACT. The first day of the workshop consisted of presentations discussing the science underpinning dietary exposure assessments. Speakers both from FSANZ and external to FSANZ (including myself) described in detail the data required to conduct exposure assessments, the techniques and assumptions used in dietary

modelling, and some of the more advanced statistical considerations faced by FSANZ in its current work. These presentations were intended to further educate participants from State, Territory, and New Zealand food regulatory agencies, as well as academics and experts in areas associated with dietary exposure assessments. Day two was more focussed on how FSANZ conducts dietary modelling in detail, with a demonstration of the DIAMOND software and discussion of some case studies.

Tasks

The first task of my peer review included identifying and/or commenting on key concerns or issues for FSANZ warranting further investigation. Some examples of these are:
- how to better use new data sources (e.g. updated food consumption data from ad-hoc surveys – can this only be done anecdotally?);
- uncertainty – how can FSANZ best express the level of uncertainty in exposure estimates;
- should FSANZ be using certain methodologies, e.g. probabilistic modelling;
- can FSANZ improve the use of, or use in a different way, adjusted nutrient intake estimates using more than a single day of food consumption data, food frequency questionnaire data, market share data, 95th percentile estimates of exposure based on consumption data from a singe 24-hour recall, treatment of not detected food chemical concentration data; and
- the use of and presenting results from brand loyal versus market weighted assessments.

The second task, presented herein, was the preparation of a detailed peer-review report including the evaluation of current procedures and suggestions for improving procedures in the future, for submission to FSANZ management and stakeholders.

Assessment

Data issues

At its most basic level, dietary modelling involves only two pieces of information: a food consumption value and a concentration of the substance of concern in that food. The product of these data is the exposure to the substance from that food. Dietary modelling in practice involves the addition of all dietary sources of intake of the substance. The scope of this addition can range from simple arithmetic to computer-generated analyses. The data, and the assumptions made in performing the additions, define the quality of the dietary exposure assessment and the results.

Food Consumption Data

FSANZ uses food consumption data from the Australia 1995 National Nutrition Survey and the New Zealand 1997 National Nutrition Survey (NNS). Both surveys used a one-day recall of all food consumed. Additionally, 10% of the participants in the 1995 Australian NNS and 15% in the 1997 New Zealand NNS were resurveyed on a second, non-consecutive day to allow the statistical adjustment of nutrient intakes. Surveys of this type are used throughout the world to perform intake assessments for ingredients, nutrients, pesticides, and other

contaminants in food. In the context of other countries food consumption surveys, the 1995 NNS was taken from a large number of consumers, providing a good basis for the assessment of Australian national food consumption. Although the data are now 10 years old, the scope and cost of surveys of this type typically render their frequent repetition impractical, and throughout the international community data of this age are commonly used. In practice, the consumption of basic food commodities does not change drastically over time, with the result that food consumption distributions for the bulk of the diet are stable. While it is true that food "fads", such as diets restricting or emphasizing specific food groups, change the public's perception of diet over time, these changes tend to be fleeting, or only change the consumption of minor portions of the average diet. For example, increases in consumption of certain ethnic foods can lead to a change in the overall consumption of a specific spice, such as cilantro. It is highly unlikely that such a change would lead to a change in the exposure to a given substance or nutrient from the overall diet of an individual or the population at large. The use of the 1995 and 1997 NNS by FSANZ for dietary modelling is completely appropriate from this perspective.

A criticism of the use of the 1995 and 1997 NNS can be made when it is used in modelling of intakes of substances that are found in foods that are infrequently consumed. For such foods, one-day recalls overestimate the mean amount of food consumed on a daily basis over a lifetime (Lambe *et al*, 2000). Depending on the specific food, this overestimation can range from 2-5 fold. FSANZ typically uses the 95th percentile of the intake distribution for its safety analyses. The use of a lower percentile, such as the 90th percentile (the practice at US FDA, which uses a two-day recall food consumption survey) might be more appropriate[3]. Food consumption surveys in the future would provide a better indication of mean lifetime food chemical intakes if they were derived from two or more days of recall data.

Concentration data

The type of information used for the concentration of the substance of concern in foods in a dietary exposure assessment is dependent on the type of evaluation being completed. Food additive evaluations may involve proposed regulatory limits or levels intended to be typically added to a processed food product. Contaminant evaluations (including pesticides) may use a mean concentration level measured in foods for an evaluation of chronic exposure to the contaminant or a concentration at a high percentile (90th, 95th, or 97.5[th], for example) of the measured distribution for an evaluation of acute (or short-term) exposure. Probabilistic exposure assessments for contaminants would involve the use of the whole concentration distribution. For the assessment of nutrient intakes, standard levels (or ranges) of the nutrient in all foods would be used.

For the concentrations of substances where censored data, that is, levels in foods below the limit of detection, are involved, a number of generally accepted techniques are available for exposure assessment. If the substance can reasonably be expected to NOT be in the food, the use of zero as concentration in that food is acceptable. If the substance is measurable in some, but not all, foods, the use of a default value, typically one-half the limit of detection is

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[3] A "rule of thumb" common among exposure assessors is that the 90th percentile of an intake distribution is typically twice the mean, the 95th is 3-4 times the mean, and the 97.5[th] is 5 times the mean. Switching from the use of the 95th percentile to the 90th percentile would be expected to lower the intake used in a safety assessment by a factor of approximately 2, which should offset the expected overestimation of mean intake due to the one-day recall survey.

common practice throughout the world. If sufficient concentration data are available to allow the presumption of a distribution of the substance in all foods, the use of such an empirically derived distribution may be appropriate. Upper and lower limits of the intake distribution can be derived by repeatedly evaluating exposure using more than one of these methods, e.g., using zero to estimate the lower bound exposure and the limit of detection to estimate the upper bound exposure to the substance. All of these techniques are used internationally.

FSANZ ensures that they document all data sources and how they have manipulated or used the data in their exposure assessment reports.

FSANZ's uses of concentration data are completely in keeping with international practice and are appropriate for their dietary modelling of ingredients, contaminants, and nutrients.

Throughout the world, default assumptions are made when the data available for exposure assessment are insufficient or are of marginal quality. Assumptions that err on the side of caution, termed conservative assumptions, are used in order to ensure that the risk resulting from consumption of the substance under investigation is not underestimated. This conservative approach is in place in most jurisdictions that perform national risk assessments, including at FSANZ.

Methodologies

Deterministic modelling

Deterministic modelling involves the use of point estimates for both food consumption and concentration levels. It can be used when only one food type, or a very limited number of foods, contains the substance of interest. The estimate can be used in a simple safety assessment, such as for an additive, but has limited application beyond such a straightforward case. FSANZ Dietary Modelling Team is fully capable of preparing deterministic models of dietary exposure.

Semi-probabilistic and probabilistic modelling

The DIAMOND software package is used at FSANZ for estimating exposures to substances found in food. The package is similar to those used in other countries around the world and is conceptually the same as that used currently at US FDA. The software contains all of the food consumption data from the Australian and New Zealand NNSs and has sufficient data to allow the determination of the consumption of all commodities that might be used to prepare a food item (recipe information). The components of the foods surveyed in the NNS are mapped to specific groupings for use in specific estimates of exposure to ingredients, contaminants, pesticide residues, or nutrients in the diet.

The software can combine a concentration level for the substance of interest in any and all foods with food (or commodity) consumptions of those foods. Since only one food concentration level is used with each affected food, this type of intake assessment has been termed semi-probabilistic. A probabilistic assessment would involve the combination of the complete distribution of concentration levels in a food with the distribution of food consumption from the NNS for that food, taken for and summed over all foods containing the

substance. Semi-probabilistic modelling of intakes for ingredients, contaminants, and nutrients is accepted practice internationally.

Probabilistic modelling is a data- and time-intensive technique that allows the estimation of a complete population-based distribution of intakes of a substance. This type of modelling involves the use of distributions for both food consumption and the concentration of the substance in foods. Any input into the model that might be variable can be included in a probabilistic model. For example, losses from preparation of foods, such as the reduction of sulfite levels during cooking could be included in a probabilistic model. Situations where there may be a variable natural occurrence of a substance that can also be used as a food additive, such as the case of nitrates can be modelled probabilistically, if necessary. Probabilistic modelling is not appropriate for all substances and would typically not be used for the simple safety evaluation of a food additive or in the case where it is expected that there would likely be no health risk from current or expected consumption in food. A safety evaluation is the case where the estimate of exposure is simply compared to a single level of acceptable intake, below which there is no appreciable health risk expected. Simpler methods, either deterministic (discussed below) or semi-probabilistic can be initially used and the results used to determine the value of a more-detailed probabilistic model. Probabilistic modelling would likely only be used to estimate what percentage of the total population may be at risk from the intake of a substance or to estimate the effect that a mitigation measure may have on such a health risk. Because of the high data and time requirements, probabilistic dietary models are not routinely prepared. The Dietary Modelling Team at FSANZ is familiar with these limitations and has the level of expertise that would be required to prepare a probabilistic model if deemed necessary.

Brand loyal versus market share models

FSANZ uses a market share model for estimating dietary exposure to some food additives. In this type of model, the ultimate exposure to the substance is reduced by the percentage of market share for the food treated with the additive. For instance, if an additive proposed for use in carbonated beverages were expected to be only used in cola beverages, and colas are known to have a 30% market share among carbonated beverages, the factor of 0.30 would be included to reduce the intake of the substance. A brand loyal model assumes that all carbonated beverages would be treated with the additive and no reduction factor would be used. The US FDA defaults to this type of model for additives. While the market share model better reflects the mean intake of the overall population, it can underestimate the intake of the additive for those consumers who are brand, or ingredient loyal (in those cases where the ingredient is "visible" to the consumer, high-intensity sweeteners, for example). The brand loyal model overestimates the number of consumers and hence the potential percentage of the population that may be at risk from consumption of the substance. The choice of market share or brand loyal models can be made on a case-by-case basis depending on the like health risk outcome or other factors. The FSANZ Dietary Modelling Team is completely aware of these factors and is fully capable of using the appropriate models.

2nd day nutrient intake adjustments

During the Science Network Dietary Modelling Workshop a presentation was made concerning the details of the statistical adjustment of nutrient intakes using the data from the second day of recall in the dietary consumption surveys (completed for 10% of the 1995 Australian NNS and 15% of the 1997 New Zealand NNS). This adjustment takes into

account the known fact that for any one day, intake of a specific nutrient is highly variable due to the variety of food choices available. Multiple days of intake are known to drive calculated intakes toward the true mean. Although a detailed understanding of this procedure is beyond my expertise, the principles behind the adjustments are well known and accepted throughout the international community. The use of such adjustments for the dietary modelling of nutrient intake is appropriate for preparing models of the effects of fortification of foods with nutrient substances.

Population Weighting

FSANZ does not currently use population weighting for its dietary modelling. This is a statistical technique where the limited number of participants in the food consumption survey (in this case the 1995 or 1997 NNS) are weighted to reflect their true percentage of a given age/sex/economic status/region/time of year tested sub-grouping. This weighting can be useful for examining the intakes of specific sub-groups of the population that may not be reflected accurately in the sampled population. For broad, national regulatory decision-making, weighting would not be expected to have a significant impact. A decision to include weighting can be made on a case-by-case basis when it is known that a model of dietary exposure for a very specific sub-group of consumers, who are not represented appropriately in the NNS, is needed. The Dietary Modelling Team is capable of determining when weighting might have an impact on a model.

Uncertainty

Uncertainty in a model arises from lack of information. Uncertainty is reduced through the collection of additional data. The variability inherent in a model is not reduced through this collection of additional data, but is more precisely defined as a result of it. Uncertainty in the FSANZ semi-probabilistic model arises from both the food consumption data, where more days of recall would reduce uncertainty and in the concentration data, where more analyses (for contaminants, additives, or nutrients) or better information on end use (for additives) would reduce uncertainty. While the models can be used to crudely quantify uncertainty, such as in the case of using a lower and upper bound level for censored data, in general such quantification is not possible. Qualitative description of the uncertainties can be helpful to stakeholders, but since it is typically the case that conservative assumptions are used in dietary modelling (and indeed there are also conservative assumptions made in the toxicological testing that contributes to an overall risk assessment), it can often be assumed that the magnitude of any possible uncertainty does not affect the outcome of the risk or safety assessment. The Dietary Modelling Team is aware of the uncertainties in its models and the data that they use, and FSANZ practice is in line with that of other regulatory agencies.

Validation

Food consumption data are never available immediately after the survey that has collected them is completed. Typically, it can take one or more years from the conclusion of the survey until the data have been readied to be released publicly.[4] When data that are being used for

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[4] The experience of the United States National Health and Nutrition Examination Survey (NHANES) is illustrative. The data collected in 2003 and 2004 are becoming publicly available as of the preparation of this report in October 2006.

dietary modelling become suspect, it is essential that some validation methodologies be developed to ensure the integrity and robustness of the resulting outcomes.

The 1995 and 1997 NNS have been criticized as being too old to account for current dietary trends. As discussed previously, the use of these data is appropriate, especially when considering staples of the diet. FSANZ has undertaken measures to validate the use of these food consumption data. A bridging study (Cook *et al*, 2001a) and a comparative data study (Cook *et al*, 2001b) were completed and published in 2001 comparing the methodology and consumption data from the previous food consumption surveys (1983 and 1985) with the 1995 NNS, establishing that intervening changes would not lead to significant changes in dietary modelling. Additionally, data derived from marketing surveys have been used, for example, to demonstrate that bread consumption (for the assessment of mandatory folic acid fortification for Australia and New Zealand), as reported in the 1995 NNS has not changed significantly in the intervening 10 years. Investigations and data such as these are essential for maintaining the credibility of the use of data as they become older. Changes in dietary staples, although rare, do occur. For example, canola oil was not used by consumers prior to the 1990s, but has now become a staple for many consumers wishing to consume unsaturated fats as part of a healthy diet. In this case, it can easily be assumed that one new staple has simply substituted for another, i.e., the canola oil replaces blended polyunsaturated oil gram for gram. The Dietary Modelling Team is aware of these issues and can fully account for them in their exposure assessments.

DIAMOND

The Dietary Modelling of Nutrition Data (DIAMOND) software package was developed in the late 1990s at FSANZ (then ANZFA) to simplify the process of preparing detailed dietary exposure assessments using food consumption data from dietary surveys. Food consumption data from the 1983 and 1985 National Dietary Surveys of Australia were originally used in DIAMOND when it was first developed. DIAMOND now contains the more updated data from the 1995 and 1997 NNSs. An IT programming consultant coded the program, based on the SAS statistical software package, and is currently still available for development of additional capabilities. The program contains an enormous amount of data, including all of the FSANZ permitted levels for food additives, pesticide residues and contaminants, other concentration data from surveys or food manufacturers, acceptable daily intakes, provisional tolerable (daily, weekly) intakes as provided in JECFA monographs, and recipes/mapping information for all of the foods in the 1995 and 1997 NNS. The input necessary for running a model using the program is the substance concentration data for each specific food or food type. Preparing these data is the most time consuming aspect of FSANZ dietary modelling, requiring an elevated level of knowledge and intuition about foods and their constituents. The generalized mechanics of the software are straightforward; for each food the software determines if there is an associated substance concentration value and multiplies this value by the consumption of that food for every individual in the NNS. The resulting intermediate intakes for each food are stored for each consumer and the next food is evaluated. Eventually, all foods for all consumers are examined and summed and a distribution of the resulting totals is available to the Dietary Modelling Team. Reports are automatically prepared that enable the Team to know how many individuals may be over an associated acceptable daily intake and how much each food type contributes to the total intake. Additional report information is available, depending on the type of analysis run. An overview of the DIAMOND process can be seen on the FSANZ website at the following URL:

http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2000/dietaryexposureasses254.cfm. This overview enables a stakeholder to gain a better understanding of the modelling used at FSANZ and is an invaluable contributor to the overall acceptance and credibility of FSANZ modelling procedures.

The DIAMOND software package contains all of the subroutines necessary to complete an exposure assessment and automatically prepare reports for internal use or dissemination to the public. It is essentially identical to the software used by US FDA, but has far greater report preparing powers. The availability of the original programmer is a tremendous asset, as it allows for modification or addition when necessary. Its ability to export outcomes into the commonly used spreadsheet program, Microsoft Excel makes data manipulation and additional report preparation simple. Its use by the Dietary Modelling Team cannot be called into question.

Other areas for development

During discussions at the offices of the Dietary Modelling Team, two topics arose that have not been considered heretofore. Currently, FSANZ does not assess exposure to or the safety of flavouring substances and also does not consider materials migrating to foods from packaging substances.

Over the past ten years, the JECFA has been evaluating the safety of approximately 2000 flavouring substances. The European Food Safety Agency (EFSA) has also undertaken safety reviews of these substances in recent years. In order to evaluate so many substances, JECFA developed a decision tree procedure to streamline the process. This process has been adopted, with some modification, for use at EFSA. Dietary modelling is not a significant segment of the procedure, as a surrogate for exposure, a point estimate termed the Maximised Survey-derived Intake (MSDI), is used at decision points in the procedure. The MSDI is calculated from estimates of poundages of flavouring substances that "disappear" into the food supply. The surveys used to supply disappearance poundages for use in the procedure have been undertaken by the flavour industries of the United States, Europe, and recently, Japan. The calculation does not require advanced modelling skills, such as those used by the Dietary Modelling Team in its evaluations. The development of a parallel procedure for use by FSANZ would be very time-consuming and resource intensive as data on the production of flavours would need to be obtained for Australia and New Zealand plus use in imported foods.

At the US FDA, the evaluation of the safety of substances migrating to food from packaging materials, familiarly called indirect additives, is a resource-intensive program, requiring a large number of full time employees. The procedures used to model exposure to these substances are completely different from those used by the Dietary Modelling Team to estimate exposures to substances found in or purposely added to foods. Any decision to begin a program for evaluating the safety of these indirect additives for Australia and New Zealand would need to carefully consider the resource implications.

Reporting

The DIAMOND package produces a large, detailed report that includes comparisons with reference health standards (such as provisional tolerable daily intakes), and other highly specific information. These reports are intended for internal FSANZ use only, and as such are both necessary and highly useful. The Dietary Modelling Team prepares written reports for FSANZ's risk managers and stakeholders, when necessary, that contain abstracted information from the DIAMOND output and other pertinent information needed for completeness. Reports prepared for publication in one form or another should be as simple as possible, while still maintaining sufficient detail to enable other qualified scientists to verify the results. The published FSANZ assessments that were assessed as a part of my preparation prior to arriving at FSANZ were clear and well documented. They are completely appropriate in the context of a food safety regulatory agency.

Guidance Documents

Stakeholders

As previously noted, FSANZ has published on its website a clear description of the DIAMOND software and the processes used to prepare exposure assessments. Guidance to the regulated industry is helpful in that it enables a party requesting a change in permissions to prepare its documentation efficiently. This, in turn, enables FSANZ to come to its decisions in a timely manner. FSANZ is currently drafting guidelines for industry for this purpose that will certainly be of benefit to industry and FSANZ.

FSANZ has a draft 1997 document "Dietary Modelling: Principles and Procedures" that outlines data requirements, modelling for food additives, contaminants and agricultural and veterinary chemicals and nutrients. This draft includes information on tiered approaches to estimating intakes, per capita data, model diets, and acute and chronic assessments. This guidance is similar in concept to that produced by WHO concerning exposure assessments. WHO is currently drafting an update to its Environmental Health Criterion Series (EHC) No. 70, which is meant to describe the procedures and data needed to do a complete safety assessment for a substance in food. The new EHC will contain a complete chapter on dietary modelling, therefore, it may be more efficient in the long run to wait until its publication before deciding if this FSANZ 1997 draft should be completed or how the revised FSANZ document could reference the EHC.

FSANZ Internal

Dietary modelling is a deceptively complex skill to acquire. It is my experience that it takes two years to become sufficiently familiar with all of the data, and to gain the necessary intuition about dietary patterns and their effects on calculated intakes. An internal FSANZ document describing the details of the use and outputs of DIAMOND would greatly help bringing new staff to a sufficient level of understanding during the overall dietary modelling education process.

Peer review of documents

Peer review of highly influential documents is essential. FSANZ is currently having documents, e.g., Total Diet Studies, peer reviewed by an expert who knows the content material (e.g. additives, contaminants, nutrients) and who also understands the exposure estimates. This practice should be continued and expanded where practical.

Publications

Very little national work on dietary modelling is published in the open literature. This is often because data submitted to the national agencies are not publicly available and the regulated industries may not allow such publication. Whenever possible, dietary exposure assessments of substances that may have a large impact on public health, such as acrylamide, recently discovered to be present in many cooked staple foods, should be published. The impact of such publication is at least two-fold; the public is assured that FSANZ scientists are participating in and contributing to important international projects, and the modellers' expertise is advertised (which has the additional side benefit of raising staff morale).

Staffing

The FSANZ Dietary Modelling Team currently consists of two permanent members and 3 temporary contract members. While 5 members of the team should be sufficient to complete the necessary evaluations in a timely manner, the temporary nature of 60% of the team presents a retention problem for FSANZ. As noted above, it takes a long time, and much hands-on experience to become truly proficient in the field of dietary modelling. This "learning curve" will have to be repeated each time a temporary contact employee leaves the team and is replaced. The addition of full-time, permanent staff will also allow a more efficient review of work prepared in the team. These internal quality control checks assure that the work product is ready in a timely manner.

Participation in international dietary modelling exercises, such as those completed by the Intake Group of JECFA is invaluable to any national regulatory body. FSANZ has allowed two of it dietary modellers to participate in a number of meetings of the JECFA since 1996. Addition of permanent staff members of the team will give FSANZ more flexibility in sending members to future meetings of the JECFA and other international symposia concerning dietary modelling practices and procedures. FSANZ should encourage the Joint Secretariats of the JECFA to include its modellers in upcoming meetings. To this end, FSANZ needs to assure that its modellers are included on the FAO/WHO rosters of experts and should encourage all of its modellers to prepare the needed documentation. Participation in the JECFA and the presence of FSANZ staff on the rosters of experts reflect back on the high quality of Dietary Modelling Team's work for FSANZ stakeholders.

Training exercises, such as those undertaken in recent years by FSANZ modellers in a number of ASEAN countries, also demonstrate the high levels of expertise available at FSANZ. These exercises should be continued, as they allow developing countries to bring additional modelling expertise to both national and international fora.

Participation in international Total Diet Study workshops, such as the one occurring in Beijing, PRC in October 2006 is also an invaluable experience for dietary modelling team

members. These workshops allow team members to learn what others around the world in the field are doing. This education is essential, as there are not many people or countries in the world doing exposure assessments (witness that the JECFA intake group rarely consists of more than 3 or 4 participants, typically with none from developing countries, South America, or Asia). FSANZ should seek to include members of its Dietary Modelling Team in as many outside activities as is allowed by workload and monetary availability.

Recommendations

1. The Dietary Modelling Team should consist of permanent appointees to ensure **skill and knowledge retention and** reduce the time spent on educating new temporary members.

2. **It is desirable that food consumption data from nutrition surveys generate several days of food consumption data for respondents, to enable more refined chronic dietary exposure assessments** to be carried out.

   Future food consumption surveys should be conducted over multiple days for all survey participants to significantly reduce the conservatism inherent in the use of the current one-day recall data. The 2007 Children's survey, intended to go into the field in early 2007 will record 2 days of food consumption. When these data become available, a 2-day average consumption for each food should be used when modelling chronic or lifetime exposure to substances in food. It must be noted, however, that due to lower body weights, food consumption for children is often 2 or more fold higher than for adults when expressed on a body weight basis, as is often necessary for comparison with toxicological standards.

3. **Efforts should be made to publish important dietary exposure assessments in the open literature thereby enhancing the scientific credibility of FSANZ's dietary modelling capability.**

   This will ensure the public's awareness of the participation of FSANZ in international evaluations, to enhance the prestige of the members of the Dietary Modelling Team, and to improve morale among team members. Publication also allows critical or supportive comments to be made available to the Team, ensuring consensus on methods and data.

4. **The transparency and presentation of the dietary exposure assessments and data in written reports** should be further enhanced.

   Reports to the public should be simple, but contain enough information to allow qualified scientists to verify the results. Public perception of science can often be influenced by how results are described. For example, the use of percentage increases often makes differences appear much larger. An exposure that is 3 times the provisional tolerable weekly intake (PTWI) does not seem to be as unsafe as one that is 300% of the PTWI. Use of many significant figures in reporting should also be avoided. In dietary modelling, and safety or risk assessment in general, two significant figures should be the maximum reported.

5. **Ensure that dietary exposure assessments are 'fit for purpose' and are appropriate for available resources. Utilization of the full DIAMOND tool is not necessary in many instances.**

   Work assigned to the Dietary Modelling Team should be relevant and an efficient use of FSANZ limited resources. DIAMOND is a very powerful tool that can answer many questions, but it should not be used simply because it can be. Priorities within FSANZ and the Dietary Modelling Team should dictate which projects can be completed in a timely manner.

6. **FSANZ should continue to seek alternative sources of food consumption data for validation of its dietary exposure assessment outcomes.**

   This is particularly true when important public health issues are involved. The continued trust of the public and stakeholders is of paramount concern.

7. **FSANZ should continue to support the use and development of the DIAMOND software package, including relevant documentation.**

   Internal training documents should be available to ease the transition of new employees into the use of this powerful tool.

8. **FSANZ should continue to encourage the participation of its Dietary Modelling Team members in international fora, such as JECFA.**

   This would include workshops, meetings, committees, and training sessions. All of these activities enhance the workings, prestige, and influence of FSANZ in international matters.

9. **FSANZ should continue its practice of having important documents and dietary exposure assessments peer-reviewed by outside experts**.

10. **FSANZ should investigate the feasibility of developing capabilities to undertake dietary exposures assessments for flavours and packaging contact materials**.

11. **Consideration should be given to how dietary exposure results derived using 24-hour recall food consumption data should be reported**.

    As exposure estimates conducted by FSANZ for food chemicals other than nutrients, are based on food consumption data from a single 24-hour recall, FSANZ should consider using a lower percentile, such as the 90th percentile, to represent exposures in the higher end of the distribution.

References

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Lambe, J., Kearney, J., Leclercq, C., Zunft, H.F.J., De Henauw, S., Lamberg-Allardt, C.J.E., Dunne, A., and Gibney, M.J. 2000, "The influence of survey duration on estimates of food intakes and its relevance for public health nutrition and food safety issues." European Journal of Clinical Nutrition (2000) **54**, 166-173.

Appendix 1 – Terms of reference

Undertake a review of all aspects of dietary modelling procedures used by FSANZ, including use of the DIAMOND computer program, including the following:

- compare the FSANZ scientific approach with current international best practice;
- assess the quality and appropriateness of the data inputs used and assumptions made in the assessments;
- review the dietary modelling techniques/methodologies used for each food chemical as to suitability;
- review the format, content and presentation of dietary exposure assessment reports in the context of a food regulatory environment;
- make recommendations to FSANZ as to improvements or adjustments that could be made to the DIAMOND program, dietary modelling procedures or dietary exposure assessment reports in the future; and
- advise on emerging food related issues or developments in methodology that FSANZ may consider in the near to medium term.