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Norwegian Scientific Committee for Food Safety

Opinion of the Scientific Panel for Nutrition, Dietetic Products, Novel Food and Allergies in the Norwegian Scientific Committee for Food Safety

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Model for assessing applications concerning food fortification

BACKGROUND

The Norwegian Food Safety Authority receives a substantial number of applications regarding the addition of vitamins and minerals to foodstuffs (including beverages). According to section 10.2 of The general regulations relating to the production and sale etc. vitamins or minerals cannot be added without special permission from the Norwegian Food Safety Authority. Norwegian authorities have traditionally based their assessment of the addition of vitamins and minerals (food fortification) on the needs of the population, or of specific groups of the population, for the nutrient in question. This practice is in agreement with Codex Alimentarius' General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 9 1987 with amendments). The practice has been reviewed in both the EFTA and the EU courts. Due to court decisions in the EU/EØS system, the Authority is now obliged to change its practice regarding food fortification and to assess whether the fortification in question will pose a risk for the population or groups of the population. The Authority has the need for a method for handling food fortification applications that ensures consumers safe products. Harmonised regulations are currently being drawn up in the EU for this area.

The Danish authorities have further developed the model compiled by Flynn and colleagues for assessing food fortification (Flynn *et al.*, Eur J Nutr 42:118-130[2003]) (Appendix 1). More details about the Danish model are given in the attached article (Appendix 2) *A safe strategy for addition of vitamins and minerals to foods* (Rasmussen *et al.*, Eur J Nutr 2005 Oct. 12). The Norwegian Food Safety Authority has asked the Norwegian Scientific Committee for Food Safety to assess the Danish model.

TERMS OF REFERENCE

The Authority has asked the Norwegian Scientific Committee for Food Safety to evaluate whether application of the Danish model will result in an assessment of food fortification that is sound on health grounds and whether this model can be applied in Norway.

On 9 November the Norwegian Food Safety Authority submitted the following additional questions, expressing a wish for an elaboration of certain points:

The Authority does not want the lowest age groups to be included in the assessment. According to § 3 of The regulations relating to foodstuffs for use for special nutritional needs, healthy babies and infants up to the age of three are defined as a separate category. The Authority does not therefore want to incorporate groups under the age of three into the fortification model.

The Authority also wants the prerequisite in the model that 25% of the energy (E%) is to be derived from fortified foods, to be reduced to 10 E%.

ASSESSMENT

The Scientific Panel for Nutrition, Dietetic Products, New Food and Allergies (Panel 7) emphasises that its basic view is that food fortification should be assessed according to the needs of the population or groups of the population, for the extra addition of certain nutrients – i.e. in accordance with the former practice of the Authority and relevant principles for the addition of vitamins and minerals in Codex Alimentarius. Due to the requirements of the EEA agreement, the Food Safety Authority is now obliged to change its practice in this area and can no longer assess food fortification on the basis of the population's needs. Viewed against this background, Panel 7 has made an assessment of the Danish model.

Panel 7'has in their assessment of the Danish model placed particular emphasis on elements in the model that must be adapted to the situation in Norway before the model can be put to use by Norwegian authorities. The Panel's proposals for the Norwegian adaptation of the Danish model (the fortification model) are given below and in Appendix 3.

Risks associated with a high intake of vitamins and minerals

Health risks associated with a high intake of vitamins and minerals are described in the assessments of the Scientific Committee for Food (SCF) in Tolerable Upper Intake Levels for Foods, published on http://europa.eu.int/comm/food/fs/sc/scf/out80_en.html, and by the European Food Safety Authority (EFSA), published on http://www.efsa.eu.int/science/nda/nda_opinions/454_en.html.

Health risks connected to/caused by a high intake of vitamins and minerals, listed? in Appendix 4, are described in the following documents: Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Preformed Vitamin A (retinol and retiny esters) (SCF/CS/NUT/UPPLEV/24 Final, 7 October 2002), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Beta Carotene (SCF/CS/NUT/UPPLEV/37 Final, 28 November 2000), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin D (SCF/CS/NUT/UPPLEV/38

Final, 16 December 2002), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin E (SCF/CS/NUT/UPPLEV/31 Final, 23 April 2003), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B_1 (SCF/CS/NUT/UPPLEV/46 Final 16 July 2001), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B_2 (SCF/CS/NUT/UPPLEV/33 Final, 7 December 2000), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Levels of Nicotinic Acid and Nicotinamide (Niacin) (SCF/CS/NUT/UPPLEV/39 Final, 6 May 2002), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B_6 (SCF/CS/NUT/UPPLEV/16 Final, 28 November 2000), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Folate (SCF/CS/NUT/UPPLEV/18 Final, 28 November 2000), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B_{12} (SCF/CS/NUT/UPPLEV/42 Final, 28 November 2000), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Pantothenic Acid (SCF/CS/NUT/UPPLEV/61 Final, 18 April 2002), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Biotin (SCF/CS/NUT/UPPLEV/55 Final, 10 October 2001), Opinion of the Scientific Panel on Dietetic products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Vitamin C (Request N°EFSA-Q-2003-08)(adopted on 28 April 2004), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Calcium (SCF/CS/UPPLEV/64 Final, 23 April 2003), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Magnesium (SCF/CS/NUT/UPPLEV/54 Final, 11 October 2001), Opinion of the Scientific Panel on Dietetic products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Iron (Request N°EFSA-Q-2003-018)(adopted on 19 October 2004), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Zinc (SCF/CS/NUT/UPPLEV/62 Final,9 March 2003), Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Copper (SCF/CS/NUT/UPPLEV/57 Final, 27 March 2003 and Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Selenium (SCF/CS/NUT/UPPLEV/25 Final, 28 November 2000).

Adverse health effects resulting from an excessive intake of individual nutrients are also described in Nordic Nutrition Recommendations 2004 (Nord 2004:13) (NNR 2004).

The fortification model

Panel 7 regards the Danish model as providing a good basis for assessment of the addition of vitamins and minerals to food, and considers that the use of the Danish model/formula for food fortification will reduce the risk of the nutrient intake of certain groups of the population exceeding the Upper Limit (UL) or the Guidance Level (GL) value. Some differences between Flynn and colleagues' model and the Danish authorities' proposals are:

1) The Danish authorities suggest that the intake of food supplements be included in the calculations
2) The Danish authorities suggest using age-differentiated UL/GL values (see explanation below in the paragraph on UL/GL values)
3) The Danish authorities assume that 25% of the total energy intake will come from fortified foods
4) The Danish authorities base their calculations on the most vulnerable groups

A general problem is the lack of intake data for several relevant nutrients in Norway. Another difficulty is that Upper Tolerable Intake Levels (ULs) have not been set for all nutrients in SCF/EFSA or NNR 2004.

The fortification model is based on the intake of vitamins and minerals and energy from the diet at the 95th percentile level in various age groups. The Panel has made use of consumption data from the comprehensive nationwide Norwegian dietary surveys conducted on various age groups: *Norkost* 1997, *Ungkost* 2000, *Småbarnskost* 1999 and *Spedkost* 1998-99. An average intake of vitamins and minerals from food supplements is added to the 95th percentile intake from the diet. Unless otherwise specified, data for the intake from food supplements are derived from The Norwegian Mother and Child Cohort Study[1]. For children under the age of three, values corresponding to the recommended daily intake of the various nutrients have been used as representative intake values for food supplements unless otherwise specified. The total intake from a normal diet plus supplements, is deducted from the UL/GL for the relevant age group, giving the maximum amount of nutrients that can be "allocated" for food fortification. The maximum amount of a nutrient that can be "allocated" is distributed over the energy intake at the 95th percentile level for the same age group. In this manner an estimate is made showing which age group is most likely to have an excessive intake of a certain nutrient.

The formula for the model is as follows:

$$ALA = \frac{MA}{EI_{95} \times PFF_n}$$

$$ALA_{25} = \frac{MA}{EI_{95} \times 0.25}$$ (corresponds to the green column in Appendix 3)

ALA = Acceptable level of addition

ALA_{25} : It is presumed that a maximum of 25 E% of the foods technically and/or in practice allow food fortification. This premise is used in all computations with regard to the level that can be "allocated" per 100 kcal.

MA (maximal allowance for intake of micronutrients from fortified foods) = UL or GL – (intake from food for the 95th percentile level + intake from food supplements).

UL = Upper Tolerable Intake Level. SCF has set ULs for the vitamins A, D, E, niacin, B6 and folate and for the minerals Ca, Mg, Zn, Cu, I and Se.

GL: Guidance Level: a value for upper intake in cases where the UL has not been set by SCF (see below).

EI_{95} = The 95th percentile energy intake

[1] http://www.fhi.no/eway/default0.asp?pid=223&oid=0&e=0&trg=ContentArea_4498&MainArea_4320=4498:0:15,2659:1:0:0:4320;4349;::0:0:0&ContentArea_4498=4504:0:15,1216:1:0:0:4320;4498;::0:0:0

PFF_n = proportion of energy from fortified foods.

The Danish authorities suggest that the calculations are always based on the most vulnerable group. Most often this will be children between the ages of one and three, but this may vary somewhat, ref. Appendix 3 *Summary*.

Example:
The most vulnerable group for vitamin D intake is one-year-old children. For this group, the 95th percentile intake of vitamin D from food is 9.6 µg per day, and the intake from food supplements is 10 µg, giving a total possible intake of 19.6 µg vitamin D/day. The UL for this age group is 25 µg, i.e. an MA of 5.4 µg. EI_{95} is 2000 kcal/day for this age group.

ALA_{25} = [5,4/ (2000 x 0.25)] x 100 = approx. 1 µg vitamin D per 100 kcal

Since § 3 of the Regulations relating to foodstuffs for use for special nutritional needs defines healthy babies and infants up to the age of three as a separate category, The Norwegian Food Safety Authority does not wish the lowest age group (up to three years of age) to be included in the fortification model. The Panel, however, is of the opinion that this model can be used for all foodstuffs (ordinary foods) eaten by all age groups. Special products for particular nutritional purposes – including specially-prepared food for children – can be assessed separately. If the age group from one to three is excluded from the model calculations, this group could be exposed to fortified products with a content of vitamins and minerals that may represent (an unnoticed) risk for the group through their intake of ordinary food. The Panel is therefore of the opinion that all age groups from the age of approximately one year should be included when using the model.

Danish authorities suggest that "light" products be assessed in the same manner as their analogous non-light products. The Panel supports this principle, but draws attention to the fact that the intake of fortified light products must also be monitored (see below).

Uncertainty is attached to a number of factors that are included in the model, and the data in the table/spreadsheets in Appendix 3 are therefore limited to two significant figures.

UL/GL values

The Scientific Committee on Foods (SCF) has set ULs for the vitamins A, D, E, niacin, vitamin B_6 and folate and for the minerals calcium, magnesium, zinc, copper, iodine and selenium. For nutrients where no UL values are available from SCF/EFSA or NNR, the Danish authorities have applied so-called GL values. The Danish assessment is to a large extent based on the report Safe Upper Levels for Vitamins and Minerals, 2003 from the UK Expert Group on Vitamins and Minerals (EVM). This report can be viewed on the website of the Food Standards Agency, UK http://www.food.gov.uk/. In the (Danish) model, GLs that correspond to the conclusions of the UK report are used for riboflavin, vitamin B_{12}, biotin, pantothenic acid and vitamin C.

GLs set by the Danish authorities have been used for the other vitamins and minerals that are included in the model – thiamin, beta-carotene and iron.

Some of the substances do not have a UL for all the age groups. The Danish authorities have extrapolated values for the various age groups from values for adults (UL or GL) on the basis of body surface area ($BW^{0.75}$).

The Panel has reviewed the data basis for the Danish assessment, examined the Danish references, and appraised the extent to which other assessments should be made for GLs in Norway. The Panel supports the assessment from the UK and Denmark, and is of the opinion that the GL values given in the Danish fortification model can be used in a fortification model adapted to Norwegian conditions in cases where a UL has not been set by SCF or EFSA. An overview of the UL/GL for each age group is given in Appendix 4.

The ULs for folic acid and magnesium are only applicable for nutrients added as fortifying agents or in food supplements, and not for those that are naturally present.

The Panel views it as important that the UL and GL values in the model are amended/corrected in agreement with any new research or new assessments – e.g. from EFSA – and will discuss such matters annually at panel meetings.

Intake calculations

The Danish authorities propose that the 95th percentile level (for food intake of the individual nutrients) of the most vulnerable group in the case of each nutrient should form the basis for calculating intake from food. The Panel supports this principle. The Panel discussed whether the 97.5th percentile level could be used, but decided that this represented data that were too uncertain. In order to identify the most vulnerable groups, the 95th percentile level of Norwegian dietary data were utilised for the various nutrients for one- and two-year olds from the *Spedkost* and *Småbarnskost* surveys, for four, nine- and thirteen-year-olds from the *Ungkos*t survey, and for various age and gender groupings from the *Norkost* survey. The results are shown in Appendix 3.

The Panel has also discussed whether the intake calculations at the 95th percentile level for men aged 16 to 29 from the *Norkost* survey are reliable since the energy intake in this group is higher than for the comparable group in Denmark. The divergence is partly due to the fact that different methods are used in Norway and Denmark, but the main cause is that some men in the *Norkost* 1997 survey have submitted an improbably high energy intake. Men in the age group 16–29 are the most vulnerable group for calcium. The Panel therefore decided to exclude men with an energy intake of more than 25 MJ from the 95th percentile level for men in the 16–29 age group. Fifteen men in the *Norkost* 1997 survey with an energy intake higher than 25 MJ have been excluded when calculating the figures given in Appendix 3.

The intake of nutrients from fortified foods that are already available on the Norwegian market are included to some extent in the calculations – for example the intake of vitamins A and D from fortified butter, margarine and milk for which general permission has been granted by the Food Safety Authority.

All the Norwegian intake calculations for the various age groups have been inserted into a spreadsheet in Appendix 3. The *Summary* accounts for the most vulnerable groups, i.e. the age group that tolerates the lowest addition per 100 kcal before the risk of exceeding the UL/GL arises. The age groups that (at the 95th percentile level) already now have an intake, from their normal diet and food supplements that exceeds the UL will have a tolerance for

fortification after the calculations that is a figure below zero (a minus figure). In practice this means that according to the model, fortification with this nutrient cannot be achieved without the 95th percentile level for the nutritional group concerned acquiring an intake that is above the UL. The minus figures have been changed to zero in the column of figures on the extreme right in the *Summary* in the appendix.

In Norway, the existing data basis is not adequate for calculating the intake of vitamin K, pantothenic acid, biotin, phosphorus or potassium. The Panel is of the opinion that for the time being Norwegian authorities can use Danish dietary data (concerning ordinary food, not food supplements) for biotin and pantothenic acid. However, the Panel has also noted that the Danish values constitute uncertain estimates. Average figures from the Norwegian mother and child survey have been used to estimate the intake of biotin and pantothenic acid from food supplements.

With regard to iodine, the data are too inadequate to allow intake calculations to be made for children and young people in Norway. Iodine is therefore not included in the Norwegian adaptation of the model but should be incorporated when data are available for all age groups.

The Danes have included magnesium from drinking water in their model. The Panel does not regard drinking water as a relevant source of this mineral in Norway, and magnesium from drinking water has therefore not been included in the Norwegian adaptation of the model.

The Norwegian authorities plan new nationwide dietary surveys. It cannot be ruled out that methods used in these new surveys may differ from those used in the survey on which the intake calculations for this assessment have been based. The Panel therefore wishes to point out that it is very likely that new dietary surveys will lead to new maximum limits for food fortification.

Food supplements

The Danish authorities suggest that intake from food supplements should be included in the calculations. The Panel supports this principle. The consumption of food supplements in Norway is very common and seems to be increasing.

With some exceptions it appears that the Danes have presumed that the intake from food supplements corresponds to approximately 1x the recommended daily intake for the various nutrients (corresponding to the average multivitamin and mineral tablet). Exceptions have been made – for example for calcium and phosphorus – since multivitamin-mineral tablets seldom contain daily doses that correspond to the recommended daily intake for these nutrients.

The Panel has decided to base its calculations on an intake from food supplements that corresponds to the average content of nutrients in the most common multivitamin-mineral supplements reported in the Norwegian mother and child survey for children over three years of age and adults. The figure of 9000 µg is used for beta-carotene, i.e. the amount that is most common in the Norwegian mother and child survey. This corresponds to the maximum amount permitted in food supplements in Norway if a factor of 6 is used for converting the intake of vitamin A (retinol) to the intake of beta-carotene.

Unless otherwise specified, values corresponding to the recommended daily intake of the various nutrients have been used for children under the age of three for food supplements. For beta-carotene in food supplements for children under the age of three, the conversion factor of 6 has been used for the recommended daily intake of retinol, i.e.300 µg x 6 = 1800 µg for one-year-olds and 350 µg x 6 = 2100 µg for two-year-olds.

The value of 10 µg has been used for vitamin D for all age groups. Five ml of cod liver oil contains 10 µg of vitamin D.

Not all foodstuffs will in practice be fortified

The Danish authorities have presumed that it is only technically possible to fortify foodstuffs that represent 50% of the energy intake (energy percentage = E%). Furthermore, they have stipulated that only foodstuffs that represent 50 E% of this will in fact be fortified. In other words they presume that for technical and practical reasons only 25% of the energy in food will be derived from fortified foods. The Panel supports the assessments made by the Danish authorities, and their? assumption that the intake of energy from fortified products will not exceed 25% provides a good margin of safety. However, this must be continuously monitored.

In the additional questions submitted to the Panel, the Norwegian Food Safety Authority requested that a special assessment should be made to clarify whether the safety margin could be reduced by assuming that 10% of the energy will be derived from fortified foods. In their article, Flynn and colleagues have indicated that surveys conducted in the United Kingdom (1999) – a country that has a liberal food fortification practice – show that approximately only 3% of the energy is derived from fortified products (Flynn et al., 2003). The Panel wishes to point out that it is not clear what this estimate is based on, and that developments may have taken place since 1999 – not least with regard to drinking patterns, including the intake of fortified beverages, among young people and adults. The Panel regards the choice of percentage for the model as an administrative issue and therefore views it as the responsibility of the Food Safety Authority. However, the Panel draws attention to the fact that a model that is based on a low percentage of energy being derived from fortified foods can prove to be a short-term choice and will require comprehensive and costly monitoring.

Results of the calculations

All the calculations that have been made according to the model – with Norwegian dietary data and Norwegian data for the intake of food supplements – are given in Appendix 3. A summary of the calculations can be viewed in *Summary* in the same appendix. The column of figures on the extreme right in *Summary* shows the amount of the various nutrients that can be added to foodstuffs in Norway (per 100 kcal) without the 95th percentile level of the various age groups acquiring an intake that exceeds the UL.

Table 1 below has been extracted from *Summary* in Appendix 3 and shows the amounts of the various nutrients that according to the calculations in the model can be added per 100 kcal foodstuff/beverage in Norway. These figures are based on 25% of the total energy being derived from fortified foods.

Table 1 Maximum amount of nutrients that can be added per 100 kcal of foodstuff according to the calculations in the fortification model

Nutrient	Max.	addition
Vitamin A (retinol)	**0**	µg/100kcal
Beta-carotene	**0**	µg/100kcal
Vitamin D	**1.1**	µg/100kcal
Vitamin E	**17**	mg/100kcal
Vitamin B_1	**2.5**	mg/100kcal
Vitamin B_2	**1.7**	mg/100kcal
Niacin	**24**	mg/100kcal
Vitamin B_6	**0.61**	mg/100kcal
Folate	**20**	µg/100kcal
Vitamin B_{12}	**99**	µg/100kcal
Pantothenic acid[2]	**9.1**	mg/100kcal
Biotin[2]	**43**	µg/100kcal
Vitamin C	**7**	mg/100kcal
Calcium	**18**	mg/100kcal
Magnesium	**0**	mg/100kcal
Iron	**0**	mg/100kcal
Zinc	**0**	mg/100kcal
Copper	**0**	mg/100kcal
Selenium	**0**	µg/100kcal

Limitations of the model

Nutritional policy authorities require special measures to be implemented for some nutrients in order to increase the intake in certain sections of the population. The model does not assess the risk of a low intake of nutrients and does not take into account the fact that food fortification targeted directly at certain groups of the population may be desirable.

Another limitation of the model is the fact that new dietary surveys will most probably lead to changes in the calculation results and thus also to the amounts of the various nutrients that the model indicates could be added per 100 kcal of foodstuff/beverage in Norway

In addition, the model does not include fortification of foods such as salt and seasonings or water (or foodstuffs that do not naturally contain energy).

Since light products are to be assessed in the same manner as their analogous non-light products, this leads to a higher content of added nutrients per unit of energy for light products than that which the model has included in the calculations. If light products (including products that provide no energy) become a major source of a nutrient, the prerequisites for the calculations in the model will no longer apply.

[2] Danish data for dietary intake have been used for pantothenic acid and biotin, and Norwegian data for intake from food supplements.

The need for monitoring

To ensure that food fortification does not represent a health risk, the prerequisites on which the model is based must be monitored:

- The intake of nutrients and energy from food and food supplements in different groups of the population
- The intake of energy from fortified foods should not exceed 25%
- Fortification of light products
- Should the Food Safety Authority decide to base the assessment of food fortification on 10 E%, the intake of nutrients must be monitored at a considerably higher level of detail than what is possible by current dietary surveys. In addition the sample size must be increased since many fortified products will be special products that are eaten by a small part of the population. A method must be used that provides information about the consumption at brand level. The Panel is of the opinion that methodological problems may arise when monitoring nutrients if the Food Safety Authority decides to use 10 E% as a basis for assessing food fortification. In this case the Food Composition Table must be upgraded to provide an overview of nutrients in foodstuffs at brand level.

Basis for the calculations

If the Norwegian authorities are to be able to make use of this model in all cases of food fortification, the data basis must be improved. The Panel wishes to emphasise the importance of maintaining and further developing the work on dietary data. Several panels need such data, and The Norwegian Scientific Committee for Food safety (VKM) has notified the ministries responsible for food matters of this need. VKM has described both the requirement for updated dietary surveys and for a better data basis for nutrients in various foodstuffs.

CONCLUSION

In principle the Panel considers that the addition of vitamins and minerals to foodstuffs should be assessed on the basis of whether this meets a need in the population or groups of the population.

Since this principle cannot actually be applied due to the obligations imposed on Norway through the EEA agreement, the Panel considers that the Danish model will reduce risk caused by food fortification. This assessment (including Appendix 3) gives a Norwegian adaptation of the Danish model as well as the amounts of the various nutrients that according to the calculations in the model can be added per 100 kcal of foodstuff/beverage in Norway. A summary is presented in Table 1.

The health hazard that may result from excessive intakes of the vitamins and minerals in question is described in opinions published by SCF and EFSA. References to these are given in this assessment.

The Panel is of the opinion that all age groups must be included in the model – from the age of approximately one year.

Monitoring is required to ensure the relevance of the prerequisites in the model. The intake of energy from fortified foods must not exceed 25%, and the data basis for the intake of energy and nutrients in the various groups of the population must be improved.

Special products as those intended for particular groups of patients or groups with special nutritional needs should be assessed separately.

ASSESSED BY

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