REPORT ON THE WORKSHOP ON MATERNAL & YOUNG CHILD NUTRITION

Report prepared by
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No moments in life are more precious and have more specific nutritional needs as pregnancy and young child age. Assuring the nutritional requirements, providing adequate dietary management and ensuring appropriate regulations are put in place are indispensable to provide the best start in life for both mother and child. Against this background a workshop was organized between scientific experts focusing on both the Indian and global perspective. This highly successful workshop was organized on April 23, 2012 at Hotel Lalit Ashok, Bangalore. In this manuscript the different angles as presented by the scientific speakers at a workshop recently organized in Bangalore will be reviewed.

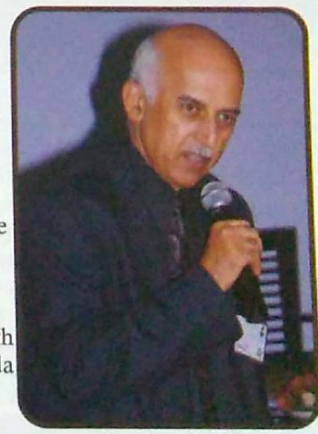
Welcome address

Dr. Sanjog Surve in his welcome note discussed the importance of nutrition. He pointed out the poor knowledge transfer between the scientific community and common man in India; He said that despite our scientific capability we do not embrace science in the walk of life, especially nutrition. He also added that the industry has a major role to play in driving consumer trend towards judicious nutrition.

He suggested following points of action:

1. The government need to encourage and support new ideas;
2. Scientific community should enable the government with decisive end to end recommendations;
3. Industry should consider local taste and food habits while delivering nutritious food.

Dr. Peter van Dael in his welcome note, highlighted three key elements – importance of infant and young child nutrition, rapidly changing regulatory environment around the world in order to catch up with the new science, and the globalization challenges in terms of products availability and media coverage. He also stressed the importance of effective interaction among various stakeholders including government, scientific community and industry in shaping regulatory framework, and suggested that such discussions must always be led by facts rather than by emotions.



Dr. Prakash highlighted the role of doctors in bringing about the trend of positive and healthy lifestyle in the society. He discussed the importance of incorporating health and wellness agenda in government policies, and cited

example of representation to the government for including nutrition security alongside food security in India. He also highlighted the importance of self regulation and urged on the industry engagement while developing regulations.

Energy and Protein Requirements During Early Life

Prof. K. Tontisirin (Mahidole University, Bangkok, Thailand)

Energy and protein intake during early life is critical for adequate growth and development. The energy and protein requirements for pregnant and lactating women, healthy infants and young children, as recently reviewed by FAO/WHO, were discussed. Principles for energy and protein requirements as well as the specific needs were highlighted. Similarly the energy and protein requirements were detailed for both breast- and formula-fed infants. The scientific rationales for the 1985 and the 2004 FAO/WHO reports were discussed and the importance of applying the lower protein and energy needs to infant nutrition were highlighted. Child malnutrition and approaches towards tackling child malnutrition were being reviewed. Finally key aspects to improve food, nutrition and health were detailed: food security is critical and requires food and nutrition education with a food culture approach. This involves interaction between all critical stakeholders, namely the scientific community, regulatory authorities and industry.

Developmental Requirements for Protein during Pregnancy

Prof. A. Kurpad (St John's Medical College, Bangalore, India)

Energy and protein requirements are particularly important as protein is the key building block for fetal growth. The scientific principles and conclusions of the 2004 FAO/WHO report were documented and reviewed against the actual data, with particular focus on India. Applying the 2004 FAO/WHO protein and energy recommendations is important to ensure adequate fetal growth. Finally, reflections were shared on how to best reduce low-birth-weight incidence, which was concluded as not manageable with single nutrients, such as increased protein intake, only.

Answering a question from participant on nutrition during pregnancy, Dr. Kurpad stressed that the balanced diet with adequate protein supply, rather than amino acid profile must drive dietary choices among pregnant women. He indicated that the exact protein requirement in pregnant women in order to ensure that the babies are neither underweight nor overweight is still not clear and may require a generation for that to get sorted out.

Maternal and Young Child Nutrition- Perspectives in Reference to RDA for Indians

Dr. B. Sesikeran (National Institute of Nutrition, Hyderabad, India)

The burden of malnutrition in India was documented. Specific data for micronutrient deficiencies (i.e., iron, zinc, vitamin A, vitamin D, vitamin B12) as well as their management through community based programs were reviewed. The role of lipids, and in particular long-chain polyunsaturated fatty acids, for development during infancy was discussed. Finally specific data for human milk lipid composition as well as lipid intake in India were being reviewed, indicating the levels vary largely and can be optimized.

From 2010 RDA recommendations it is noted that requirements of iron are lower than what was recommended in the RDA in 1989. This is based on the studies in last few years indicating that the extent of bioavailability of iron in the diet is more that what was presumed. Also it is observed that in presence of vitamin C the iron requirement is slightly lower.
Further he discussed 3 studies which show that as the child's age advances there is progressive depletion of zinc. Zinc status from birth up to 9 months of full term, pre term and formula fed babies is almost similar. At 9 months of age formula fed babies get lower zinc than those who are breast fed both who are full term and pre term. Hence there is need to address the zinc levels in the formula.

He also highlighted that Zinc intake in children of age group 15 to 18 months are much lower than RDA. Zinc deficiency is an issue and need to be addressed in the regulations. He pointed out that in the regulations zinc is considered as contaminant rather than a nutrient.

NNMB data show that there is no significant improvement in macronutrient deficiency since 1970. Likelihood of replacing the micronutrient deficiency through natural sources is less. The foods need to be fortified to address this issue. Also adequate nutrients are required to be provided to adolescent girls to address the concern of low birth weight babies.

He also discussed the importance of DHA and ARA for infants and young children.

Answering a question whether nutrient requirements in Indian standards must be expressed per 100 kcal rather than per 100 g, Dr. Sesikeran mentioned that for easy understanding of manufacturers and regulators the requirements are expressed per 100g; and that labelling may carry nutrient contents expressed as both per 100 g as well as per 100 kcal. Addressing another question from audience regarding the use of Iron EDTA, which has higher bioavailability, as the source of iron in infant nutrition products, he said that it may require submission of more data on safety for review by the scientific panel.

Indian Regulatory Standards for Infant Formulas in View of Evolving Science

Dr. V. Sattigeri (Central Food Technological Research Institute, Mysore, India)

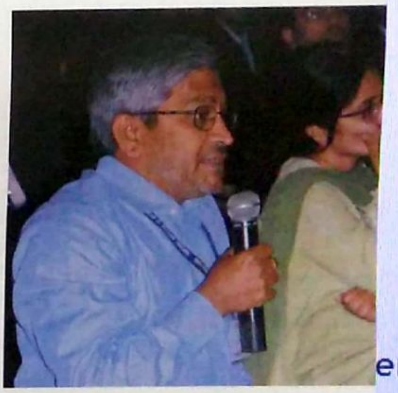
Dr. Sattigeri gave an overview of regulatory standards governing infant nutrition products in India. He discussed that the regulations under Food safety & Standards Act, 2006 give definitions of infant nutrition products and lay down compositional, microbiological and quality requirements.

He compared Codex standard for infant formula (Codex STAN 72-1981) with the Indian standards under Food Safety and Standards Regulations (FSSR) and pointed out some major differences. He pointed that the FSSR requires min 12% milk fat in infant formula, where as such a limit is not set in codex; that Codex specifies a range for linoleic to alpha linolenic acid ratio where as FSSR does not. Precooked and gelatinized starches are allowed to an extent of 30% of total carbohydrates in codex. He then highlighted the differences in compositional requirements set out by both Codex and FSSR. He pointed that along with minimum requirements, Codex also specifies maximum (or GUL) limits for vitamins and minerals. Minimum iron requirement specified in FSSR is more than double than that given in Codex. Minimum requirements for Copper and Manganese specified in FSSR are much higher than those specified in the Codex. Iodine requirement as per FSSR is much lower than that of Codex requirements. Based on these observations, Dr. Sattigeri suggested that the minimum requirements of these minerals must be revised to ensure adequate nutrition in Infants. He also suggested that the Chromium and Molybdenum levels and sources may be specified in the revised standard on Infant formula.

Dr. Sattigeri emphasized on the differences in the absorption of milk fat and vegetable fats in infants, and pointed that vegetable oils with predominantly unsaturated fatty acids are absorbed more completely than milk fat. He pointed that it is not only the fatty acid composition but the arrangement of fatty acids on glycerol molecule that is important in digestion and absorption.

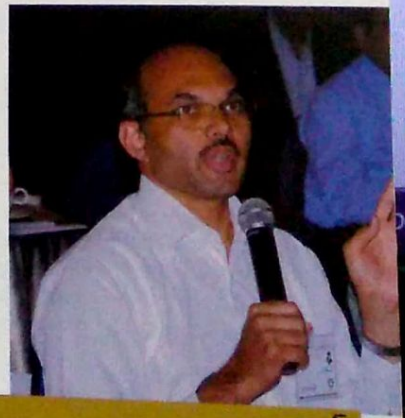
He suggested that nutrient declaration per 100 kcal is more apt from physiological point of view. He recommended that the long chain polyunsaturated fatty acids such as DHA and ARA must be allowed at the levels specified in Codex. He recommended that the list of Food additives and sources of micronutrients may be adapted from codex. He also pointed that the revised standard must contain a provision for the addition of precooked/ gelatinized starch at level not exceeding 30% of total carbohydrates.

Answering a question from participant, Dr. Sattigeri repeated his suggestion that the Iron requirement in Indian standard for infant formula must be revised in line with the revised codex standard. He explained that the codex had revised Iron requirement from 1 mg to 0.45 mg per 100 kcal based on 2005 recommendations of ESPGHAN who had analyzed infant's actual requirement of iron before 6 months age. He also mentioned that folic acid content must be increased from current 20 mcg to 50 mcg per 100 g to match requirements as per codex standard. In totality he suggested that the iron requirement must be reduced and folic acid requirement increased to match codex specifications which are based on risk assessment studies. He concluded suggesting that the regulations must be dynamic to keep pace with the latest developments in nutrition science.



Addressing a question on Zinc contents in Infant formula, Mr. Nair said that the zinc requirement must be revised based on Indian RDA values, and that the current requirements are indicated from the 'contaminant' point of view.

Mr. Shrinivas Bhat suggested that the Ca:P ratio given in FSSR for preterm formula must be revised, and suggested to provide a range from 1.2 to 2 instead of just one ratio as given in current standard.



Dietary Management of Medical Conditions in Infancy- Indian Scenario

Dr. B. Raju (Chennai): Infants with specific nutritional needs such as preterm infants, infants with allergic manifestations, infants with inborn errors of metabolism or malabsorption syndromes, have special dietary needs, different from those of normal healthy infants, in order to support normal growth and development.

Each of the specific medical conditions, dietary specificity of the medical conditions as well as ways for their dietary management was reviewed. These formulas for special medical purposes are critical and indispensable for the dietary management of infants with specific disorders. An overview of specially designed formulas for the dietary management of these disorders was been presented. At present these formulas are not available in India as there is not specific regulation that enables these special formulas to be registered and commercialized in India. A clear request for making these formulas available to the health-care community and the infants that are at need in India was launched.

Dr. B. Raju started his discussion highlighting that the children in India currently are not getting adequate food and nutrition. He pointed that cow milk protein allergy (CMPA), mal-absorption and metabolic disorders are specific conditions in infants and young children, where adequate diet and right nutrition can make a huge difference. He pointed that protein allergy which was considered uncommon in India has become a common occurrence in recent years. He brought out the differences between cow and human milk protein and pointed that β-lactoglobulin is the worst offender in infant nutrition. He indicated that the incidence of cow milk protein allergy (CMPA) in India is 0.5 – 1%, and that most of the affected young children tend to overcome the associated GI symptoms by the age of 4 years. He stressed that early introduction of cow milk to infants is one of the major risk factors for developing allergy. Inadequate breastfeeding and early introduction to solid foods are other major factors.

He discussed the commonly used feeding alternatives for infants with CMPA in India that include legume based foods, yoghurt and soy based formulas; and suggested that ideally hypoallergenic foods must be given. He pointed that the enzymatic hydrolysis is the most efficient way to produce hypoallergenic formula for infants with CMPA.

He discussed AAP recommendations on dietary management on CMPA which includes avoidance of soy formula; and preference to extensively hydrolyzed formula over partially hydrolyzed formula.

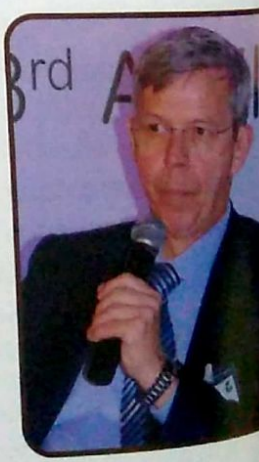
He pointed that the formulas developed specifically for dietary management of infants with CMPA, which includes some of the brands of global reputation are unfortunately not available in India, and that the pediatricians have to rely on soy based formulas as there are no alternatives. He said this is a wrong approach, as infants with CMPA are generally allergic to soy protein as well. He discussed additional nutrient requirements in preterm infants to achieve 'catch up' growth and pointed that mothers milk of preterm infant can provide adequate 'extra' nutrients only for first 10 days, but later it reverts to composition similar to mother's milk of term infants. Hence supplementation becomes necessary to ensure adequate catch up growth. He mentioned that the exclusive preterm formula feeding can not be recommended as mother's milk carries many other advantages. He pointed that the formulas and human milk fortifiers available in Indian market are fairly primitive.

In conclusion he urged that the regulations must make provisions to bring life saving high quality formulas to India.

Answering a question on unavailability of FSMP in India, he said that he can't find a justifiable answer for that and said that it is very difficult to meet the needs of such infants with disorders. Dr. Sesikeran clarified that so far these products were caught in between drug regulations and food regulations and assured that a category would be formed under new regulations to regulate distribution and sale of such products.

Mr. Srinivas Bhat commented on the issue highlighting two major hurdles - that the Indian standards for infant nutrition products are not aligned to the global standards; and second, that the mandatory BIS certification required for infant nutrition products, which specifies the use of certain outdated testing methods that may not be practically possible. He opined that the affordability is certainly not an issue.

Meeting Dietary Needs of Infants: Scientific and Regulatory Insights



Prof. Dr. B. Koletzko (Munich, Germany): Infants during the first month of life are solely dependent on a single food source, ideally breastfeeding as defined by WHO. WHO recommends exclusive breastfeeding for at least 6

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months, but if breastfeeding is not possible supports a nutritionally adequate breast milk substitute as alternative. Provisions for breast milk substitutes or infant formula have been defined by regulatory authorities as well as by Codex Alimentarius, the UN FAO/WHO body established to elaborate global standards for safe and nutritious foods as well as to promote/ensure free trade. Regulatory standards, in general, and for infant nutrition in particular, are to be aligned with the latest scientific findings in order to assure the highest nutritional and safety standards for infants and young children. Against this background an international expert group assisted the elaboration of the revised Codex infant formula standard (Codex STAN 72-1981).

The compositional criteria of infant formula meet the nutritional needs of healthy infants. However, some infants suffering from specific metabolic or functional disorders require special nutritional needs in order to comply with their medical conditions. For these infants, the infant formulas have to be specifically adapted to meet their special dietary requirements. These formulas are called formulas for medical purposes and generally are different in composition from normal infant formulas for some specific nutrients.

Examples of special medical conditions, such as phenylketonuria, galactosemia or severe cow milk protein allergy, and the simple, efficient way how infants with these medical disorders can be effectively managed through dietary intervention have been reviewed. Adequate management enables these infants to develop normally, whereas inadequate management, using normal infant formulas, can lead to irreversible damage or even in some case to death. The availability of a regulatory framework such as established by Codex Alimentarius or European Commission is indispensable to provide these dietary management options to all infants and assure that all infants, even those with medical disorders, have access to normal development and growth.

Prof. Koletzko started his discussion stressing that feeding in Infancy is more important than at any other stage of life. He pointed that there is evidence to support that early nutrition modifies the risk of later development of non-communicable diseases such as obesity, diabetes etc. He mentioned, though breast milk is the best possible source of nutrition for infants, it is very important to have high quality infant formula, as the volumes of infant formula consumed are significantly high because there are instances when infants cannot be or should not be breast fed, wherein the use of unmodified animal milk must be discouraged.

He pointed that providing cow milk in first year of life must be avoided as it leads to inadequate nutrition and may aggravate iron deficiency, hence should be avoided. He suggested high protein intakes in infancy may lead not only to increased weight gain but also long term obesity. He reiterated WHO statement that those infants who are not fully breast fed must receive high quality breast milk substitutes. He discussed the evolution of infant formula through 19th and 20th century and pointed that pediatric nutrition science has evolved from 'more is better' notion to 'balanced intakes' strategies.

He discussed how ω-6 and ω-3 fatty acids compete for same enzyme system in their metabolism and pointed that too much Linoleic acid may adversely impact DHA incorporation in infants, which have untoward effects in eye and brain development.
He cited a randomized study that indicated iron supplementation in iron sufficient infants resulted in significantly lower length gain in them. He also pointed that feeding infants protein at levels found in human milk helped to maintain low BMI, whereas higher protein consumption in the first year of life resulted in significantly high BMI even at the age of 6. He stressed that 'more is not better' and that adequate and balanced nutrition should be the focus. He cited the example of Codex adapting ESPGHAN recommendations for revising infant formula standard, where maximum limits were laid down on many nutrients, not present in older recommendations.

He discussed the codex standard on infant formula which has two sections: one for regular infant formula and the other for formulas for special medical purposes (FSMP). He reiterated that FSMP are required for the dietary management of specific disorders such as inborn errors of metabolism, abnormal GI function and allergies. Prof. Koletzko highlighted the importance of FSMP in dietary management on infants with disorders through some examples: he discussed a couple of examples of children with phenylketonuria (PKU), a metabolic disorder; and described the dietary management of such children that involves severe restriction on Phenylalanine (Phe) intakes together with monitoring its plasma levels. Such infants could be partially breastfed and

given a FSMP that provides all essential amino acids, generous amounts of Tyrosine and absolutely no Phenylalanine. The result was completely healthy and normal children. He mentioned that early diagnosis and proper dietary management of phynylketonuria that would enable an individual to grow as a healthy child and be a productive member of society is the most worthwhile investment in healthcare.

He also discussed an example of an infant with galactosemia, who was treated to a normal healthy infant by using lactose free infant formula, excluding breastfeeding and regular infant formula from the diet. In another example he showed how an infant with persistant diarrhea was cured by giving low lactose formula.

He stressed the effect of malnutrition on IQ of children, and hence their productivity and wealth creation ability later in life and suggested that investment in adequate nutrition is critical for any society. He discussed the importance of using a nutrient dense special formulation for malnourished infants. He stressed the importance of using specific formulations to different age groups, especially in infancy. He also discussed the importance of hypoallergenic FSMP in treating CMPA by giving example of an infant allergic to external proteins in her mother's diet which transferred in small amounts into her breastmilk. The baby was cured by exclusive feeding of a hypoallergenic formula based on extensively hydrolysed protein. He suggested that the soy formula intake as an alternative in infants with CMPA must be avoided at least during early infancy.

In the end, he discussed the features of FSMP and stressed on their proper usage.

He concluded saying that breastfeeding must be actively promoted, that high quality infant formula based latest scientific developments must be made available to infants which are not fully breast-fed, that infants with certain disorders who don't do well with breastfeeding/ regular infant formula must be made available FSMPs which are specifically designed for such disorders.

Overview of Global Regulations for Formulas for Special Medical Purposes (FSMP)

Dr. Peter Van Dael (Mead Johnson Nutrition, Evansville, Indiana, USA)

Infant nutrition regulations are put in place to assure safe and nutritious infant foods that meet the nutritional needs during early life as sole source of nutrition or as complementary food. Regulations are to be updated as needed to ensure new scientific findings are taking into consideration so that state of art nutrition and safety is provided to all infants. Infant formulas for special medical purposes are indispensable for the dietary management of infants with special medical disorders and require appropriate regulatory provisions. The revised Codex Alimentarius standard for infant formulas (Codex STAN 72-1981) laid down a specific section for these special formulas. The key principles of this standard are that the composition of these formulas should be based on scientific principles that support the needs of infants with special medical disorders. Additionally these formulas require special labeling conditions as well as to be used under medical supervision.

The regulatory provisions laid down by Codex Alimentarius, are similar to those defined in the USA, the European Union as well as Australia and New Zealand. The availability of regulatory provisions has been a key driver for the availability and the development of formulas for special medical purposes in both USA and European Union Member States. These regulations can be used as a reference to implement locally a regulatory standard for FSMP.

Absence of a regulatory framework has also been an obstacle to make these formulas available in India. It is was recognized and agreed that a regulatory provision for FSMP is required urgently in India, that it is desirable to use the Codex Alimentarius standard as a reference for India and that the learning from US or European Union can guide the implementation of FSMP in India.

Peter van Dael pointed that the regulations can generate trust only when science is adapted and adopted in them. It's a 360 degree effort – regulatory authorities, scientific bodies and manufacturers must work together to generate trust among consumers. He stressed that the risk assessment and risk management are two key elements of regulations, and it is very important to generate consensus among stakeholders. He highlighted that the infants with specific medical conditions need formulas for special medical purposes (FSMP) addressing those specific disorders. For example, infants with inborn errors of metabolism must be given certain specific formulas containing protein equivalents.

He suggested that the regulatory framework must be evolved to cover these FSMP. He pointed that globally,

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regulations provide compositional flexibility to address the specific disorders and meet the specific nutritional requirements in infants with certain disorders, with a condition that the nutritional adequacy and safety must be scientifically demonstrated. He mentioned that the Codex standard has a separate section that deals with FSMP; US have a separate section on 'exempt formulas' in the Infant Formula Act that covers FSMP; and In the EU, FSMP directive regulates these products.

Discussing the procedures followed to place a FSMP in the market, he described that the US have a system wherein a petition is submitted by the manufacturer citing the rationale along with the supporting studies for assessment, the US FDA website maintains a list of such approved exempt formulas in the market; in EU, the manufacturer is required to notify the competent authority of the member state that gives the scientific opinion on the product.

He said a similar system is in place in Australia - New Zealand as well.
In conclusion, he stressed the need to have compositional flexibility and specific labelling requirements incorporated into the FSMP regulations.

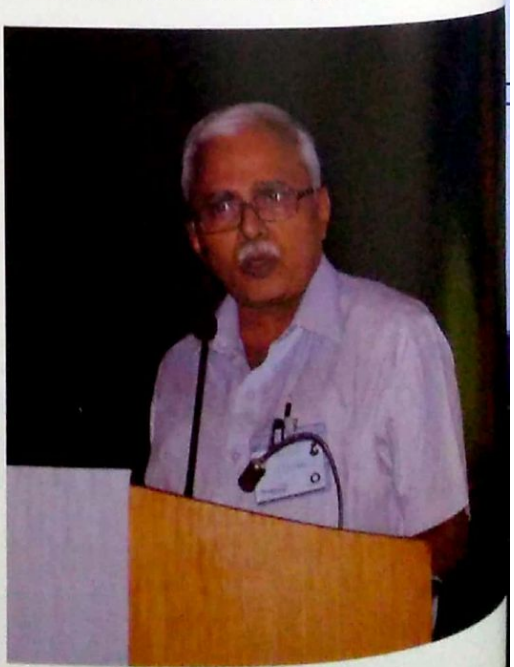
Answering a question on non-availability of FSMP in India, he pointed that marketing of such life saving products is rewarding for any infant nutrition company, and said that the regulations must allow room for development of such products and that enforcing authority must clearly understand the rationale behind such products.
Answering a question on the requirement of milk fat in infant formula, he pointed that there is no nutritional basis for adding milk fat in infant formula and that there should not be any regulatory requirement on min content of milk fat in infant formula.

Panel Discussion:

Dr. Shenaz Vazir emphasized the practice of exclusive breastfeeding, its advantages on cognitive and socio-emotional developments and suggested that the healthcare system and family must educate and support new mothers on breastfeeding. She discussed the importance of adequate complementary feeding on growth and development and stressed on holistic approach to nutrition.

Dr. Jamuna Prakash highlighted the importance of hygiene and sanitation along with adequate nutrition, and discussed the importance of awareness, education and making available the nutritional advice to every section of the society.

Dr. Appu Rao discussed the importance of having regulatory aspects in place so that India may not lag behind in providing adequate nutrition. He called for effective and focused delivery systems in ICDS for micronutrient supplementation for mothers and young children. He stressed the importance regulatory provisions allowing FSMP into India and being used effectively. He pointed that the micronutrient supplementation



must be based on food based approach.

Dr. Peter van Dael stressed the importance of research in nutrition science conducted in different parts of the world, especially the backward countries. He discussed the importance of creating nutritional education and awareness among children. He suggested that regulations may be evolved effectively through interactions among individuals who may have different opinions.

He discussed the importance of having implementable regulations in place, and the necessity to put emerging conclusive science into regulations. He stressed the importance of de-connecting relevant from non-relevant and minor discussions in shaping regulations. He also discussed the need to focus and un-focus on the research areas.

Dr. Anura Krupad highlighted the lack of clarity on feeding requirements during pregnancy in terms of protein and other micronutrient requirements. He agreed with the comment from Prof. Koletzko that the protein requirements in current Indian regulations are higher than the recommended P/E ratio for that age group. He discussed that some economic assistance may be planned for people who cannot afford life saving FSMP products. He pointed the importance of targeted entitlements for social welfare.

Dr. Anuja Agarwala said that the life saving FSMP products must be made available in India. She stressed the need of education and awareness to promote child health.

Dr. Sasidhar Rao recommended that the FSSAI must look into the legislation to make FSMP products available in India to address the pediatrician's concerns. He suggested that the industry and institutions in India must come up with products necessary for the country, which are based on the materials available in the country.

Dr. Vongsvat pointed the missing link between translating research into practice at the grassroots level. She reiterated the importance of public awareness of maternal and young child nutrition and brought out its impact on national economy and human well being.

Dr. Pai stressed the importance of encouraging nutrition awareness programs through media.
Dr. RBN Prasad highlighted the importance of speedy clearance of industry submissions and urged for the quicker conversion of recommendations into regulations by the FSSAI.

Dr. Prakash suggested that Codex must take into consideration local knowledge and practices especially from East, while formulating guidelines and

standards. While answering a question on Public Private Partnerships he stressed the importance of collaborating with the NGOs, academic and R&D bodies, and most importantly industry; and pointed that authorities are working with the industry like never before.