



26 February 2004

**SUBMISSION ON THE PROPOSED REGULATIONS RELATING
TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN
GOVERNMENT NOTICE NO. R.1328
DEPARTMENT OF HEALTH
26 SEPTEMBER 2003**

Introduction

This submission comments on the Draft Regulations Relating to Foodstuffs for Infants and Young Children (“the Regulations”) published in terms of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972.

In summary, the current Regulations do not take into account the realities and challenges brought by HIV/AIDS. This can be addressed if the Regulations are redrafted to incorporate the various recommendations issued by the WHO (World Health Organisation) in connection with HIV and infant feeding. In this submission, we highlight some of the sections that are in need of particular attention and relate to the following:

- ⌘ “Breast is always best” (section 3)
- ⌘ Promotion of formula feed (section 7)
- ⌘ Donations (section 9)
- ⌘ Information, educational material and other material (sections 13 & 14)

Breastfeeding is universally acknowledged as the best source of nutrition for infants. As a result of poverty and lack of access to basic services, breastfeeding is often the only option women have available to them to adequately provide for their infant’s nutritional needs. It is important for the government to put in place a legal framework that regulates the provision of

breastmilk substitutes. The Regulations are an attempt to comply with the government's commitments under the World Health Organisation's International Code of Marketing of Breastmilk Substitutes of 1981 ("the Code").

The AIDS Law Project (ALP) however notes with concern the contents of the proposed Regulations as it relates to formula feeding of infants. It would seem from the proposed Regulations that the Department of Health strongly advocates the use of breastmilk over formula feed for babies, without regard for circumstances within which it would be inappropriate to do so. This is a particularly problematic position to take in a country with an explosive HIV epidemic in which 26.5% of pregnant women using public sector health facilities tested HIV positive in 2002.¹

A known form of HIV-transmission is through breastmilk, in which a mother with HIV can transmit the virus to her baby through breastfeeding. It has been scientifically established, that where formula feed is available, safe, accessible and affordable, that mothers with HIV should formula feed their babies exclusively for a period of not less than six months, as to reduce the risk of transmission. The potential dangers of breastfeeding in such circumstances have been pointed out by Department of Health in its following publications: *Breastfeeding & HIV – An Information Booklet for Health Workers in South Africa*², *Feeding of infants of HIV positive mothers*³ and *Prevention of mother-to-child HIV transmission and management of HIV positive pregnant women*.⁴

The Department has also made it clear that pregnant women should be counselled about the risk of HIV transmission and all feeding options available⁵ and that each woman should be put in a position to elect the option that she deems best for her individual circumstances and her child. The ALP supports this approach as it is in line with a woman's rights to bodily and

¹ *National HIV and Syphilis Antenatal Sero-prevalence Survey in South Africa, 2002*, National Department of Health

² Department of Health, produced by the Provincial Administration of the Western Cape, January 2002.

³ HIV/AIDS Policy Guideline, HIV/AIDS and STD Directorate, Department of Health, August 2000.

⁴ HIV/AIDS Policy Guideline, HIV/AIDS and STD Directorate, Department of Health, May 2000.

⁵ Also see "Circular Minute on Prevention of Mother-To-Child Transmission of HIV" 16 April 2002, Available from <http://www.doh.gov.za/docs/>

psychological integrity⁶, privacy⁷, dignity⁸, access to health care services⁹ and access to information¹⁰ as guaranteed by the South African Constitution.

International Guidelines on HIV and infant feeding

In October 2000, the World Health Organisation (WHO) convened a *Technical Consultation* on new data on the prevention of mother-to-child transmission. Since then, the World Health Assembly has adopted a *Global Strategy for Infant and Young Child Feeding* which promotes exclusive breastfeeding for the first six months of life, with adequate and safe complementary feeding from age six months and continued breastfeeding for up to two years and related maternal nutrition and support. Such breastfeeding is promoted for HIV-negative women and women who are unaware of their status.

As part of this *Global Strategy*, an *HIV and Infant Feeding Framework for Priority Action* was developed. This Framework has been endorsed by the WHO, UNICEF, UNAIDS, WFP and other international organisations. The Framework proposes five priority areas for national governments in the context of the *Global Strategy for Infant and Young Child Feeding*:

- Develop or revise a comprehensive national infant and young child feeding policy, which includes HIV and infant feeding
- Implement and enforce the International Code of Marketing of breastmilk substitutes and subsequent World Health Assembly resolutions
- Intensify efforts to protect, promote and support appropriate infant and young child feeding practices in general, while recognising HIV as one of a number of exceptionally difficult circumstances
- Provide adequate support to HIV-positive women to enable them to select the best feeding option for themselves and their babies and to successfully carry out their infant-feeding decisions
- Support research on HIV and infant feeding, including operations research, learning, monitoring and evaluation at all levels, and disseminate findings.

The Regulations should be seen within the context of the above priority areas as identified in the Framework.

⁶ Section 12 of the Constitution of South Africa, 1996.

⁷ Section 14

⁸ Section 10

⁹ Section 27

¹⁰ Section 32

Recommendations

We would therefore like to draw your attention to the following points in the proposed Regulations that we think compromise the Department's other policy initiatives on HIV and infant feeding options:

1. The need to develop a comprehensive national infant and young child feeding policy, which includes HIV and infant feeding

The WHO urges decision-makers to take steps to ensure that health-care providers and counsellors are aware of, and able to implement, recommendations on infant and young child feeding, **including HIV and infant feeding, at various levels.**¹¹

Currently, the Regulations promote breastfeeding and regulate the feeding of infants in general, whilst a separate policy deals with infant feeding in relation to mothers with HIV. It has been our experience that, without adequate information on the risks and benefits of breastfeeding in the context of the HIV epidemic, health care workers find it difficult to provide the necessary support to women with HIV to facilitate their decision about infant feeding. As the Regulations currently stand, they promote breastfeeding and do not provide the necessary framework in which health care workers and counsellors can adopt a nuanced approach to their work that considers the needs of women in general and well as the specific needs of women with HIV. The WHO recommends a more comprehensive approach.¹²

The Guidelines also note that such a comprehensive approach could reduce the stigma and discrimination faced by women with HIV and would facilitate their integration into general maternal health facilities. In South Africa, where various clinics and hospitals have embraced the Baby Friendly Hospital Initiative and a "pro-breastfeeding" approach, the environment does not always enable women with HIV to make a balanced decision on infant feeding. The restrictive wording in the Regulations could facilitate such discrimination and coerce women into deciding to breastfeed.

Regulation 3(1)(a) requires manufacturers to provide the following message on formula feed: "Breastfeeding provides the best food for your baby and

¹¹ HIV and Infant Feeding: Guidelines for Decision-makers (WHO, 2003)

¹² HIV and Infant Feeding: Guidelines for Decision-makers (WHO, 2003, p11)

reduces the risk of diarrhoea and illnesses”. In the absence of adequate counselling on feeding options, such a message could confuse and coerce women with HIV who have decided to use a breast-feeding substitute.

Regulations 14(1) and (2) direct health care workers and other to “promote, support and protect breastfeeding”, while Regulation 14(3) seems to instruct health care workers to actively discourage mothers to use formula feed. These provisions need to be modified to include information on HIV transmission and women’s choice of feeding methods. Without such amendments, the regulations unjustifiably limit women’s constitutional rights.

A comprehensive national infant and young child feeding policy could also serve to bring together under one framework the various other government initiatives aimed at providing nutritional support to infants and young children. The various disparate policies in infant and young child feeding makes it difficult for parents to determine the various options open to them in accessing food for their children.

2. The need to implement and enforce the International Code of Marketing of Breastmilk Substitutes

By incorporating HIV into the Regulations, the Regulations would bring women with HIV under the protection of the Code by:

- Protecting children fed with breastmilk substitutes by ensuring that product labels and health care worker advice include information on safe preparation and use.
- Ensuring that the product is chosen on the basis of independent medical advice.

In this regard the restrictive wording in the Regulations does not adequately provide for the needs of women with HIV, in terms of the Code. Regulation 7, for example, prohibits any person from participating in promotions regarding formula feed whilst the definition of “promote” is particularly wide. This section might have the unintended consequences of persecuting health care workers or counsellors who counsel pregnant women with HIV about feeding choices available to them. Whilst the Regulations ensure that health care workers are not unduly influenced by companies when providing information about feeding options, Regulation 14 could militate against the provision of “independent

medical advice” by promoting breastfeeding without adequately providing for women with HIV and in other difficult circumstances.

3. The need to provide adequate support to women with HIV to enable them to select and implement the best feeding option for themselves and their babies

In the context of HIV, where mixed feeding has been indicated as posing an increased risk of HIV transmission, it is important that women who choose to use breastmilk substitutes are able to access a constant supply. Donations of formula milk should be treated with caution, as this does not always ensure a constant supply. The Code and Regulations both deal extensively with the issue of donations of breastmilk substitutes by companies. We urge the Department to incorporate the specific recommendations identified by the WHO.¹³

With regard to HIV the various guidelines suggest that the government rather provide free or subsidised breastmilk substitutes or negotiate reduced prices for formula milk from the companies. The provision of low-cost breastmilk substitutes to women with HIV is included in Regulation 9 provided that such low-cost products are procured through normal channels and not provided to only specific facilities [section 9(5)]. The government is encouraged to pursue the various legal mechanisms open to it to procure breastmilk substitutes at low cost.

Regulation 9(3) seems to make provision for donations to hospices, orphanages and places of safety. We assume that the specific designation of such places as opposed to other institutes relates to the fact that breastfeeding is unlikely and therefore not dissuaded by such donation practices. By limiting donations to such institutions however, the Regulation has the potential to limit the ability of other organisations providing care to infants from accessing much-needed donations. For instance where organisations provide products to infants and young children in communities as part of home-based care initiatives where parents are not in a position to feed their children.

¹³ HIV and Infant Feeding: Guidelines for Decision-makers (WHO, 2003, p17-19)

Articles 6.6 and 6.7 of the Code should be incorporated under Regulation 9 to provide that institutions or organisations as opposed to companies provide donated products to people outside of the institution and to place responsibility when distributing donated products, on donors, institutions and organisations to ensure a constant supply.

The right of women to choose whether to breastfeed or not, implies that women should also be given the means to implement their choice. Without the resources to access a constant supply of formula feed, women are denied the right to choose such an option. The Regulations prescribe that, where health care workers inform women of their infant feeding options, they should explain that there are prohibitive costs involved in accessing formula milk. Whilst this provision aims to discourage the use of formula feed in the general population, it places women with HIV and women who cannot breastfeed due to ill health or work, in a very difficult situation. In essence, it is poor women who are denied the opportunity to implement their informed choice.

The WHO specifies that, in terms of the Code, mothers should not be given samples or small amounts of breastmilk substitute. Women with HIV who choose to use breastmilk substitutes should be given “sufficient supplies **for as long as their infants need it**, usually at least up to 12 months” [HIV and Infant Feeding: A guide for health-care managers and supervisors (WHO, 2003, p10)]. We support this principle.

Caution has often been expressed that the provision of free breastmilk substitutes would discourage breastfeeding. The WHO has suggested that women with HIV who choose to breastfeed, should be provided with nutritional support [HIV and Infant Feeding: Guidelines for Decision-makers (WHO, 2003, p19)]. Irrespective of their feeding choice, women should be provided with support to ensure the maintenance of their own health. It is hoped that the provision of antiretroviral treatment in the public health sector will facilitate women’s choices by reducing their risk of HIV infection through breastfeeding and improving their general health. By ensuring support for women’s decisions, women would also find health facilities more accessible which will, in turn, facilitate their ability to access services to improve their own and their child’s health.

To enable women to make the best decision for themselves and their babies, they would need adequate information. Health care workers and counsellors

should be given training to enable them to provide women with this information. The definition of a “health worker” in the Regulations is broad enough to include counsellors but this can be specifically stated to avoid uncertainty.

The wording of the Regulations can be seen to discourage the provision of information. It would seem that Regulation 13 prohibits the dissemination of information on formula feed. This is extremely problematic in view of the right of access to information, and the need for pregnant women with HIV to be presented with all the latest scientific information on safe feeding practices. Care should also be taken not to create an environment in which any woman who chooses to use breastmilk substitutes is stigmatised as a result.

The WHO has emphasised that women should be supported in their infant-feeding decisions.¹⁴ The WHO lists a range of information that should be given to women once they have made their decision, to ensure that infant feeding happens with the least risk of transmission of HIV and provides the best nutritional support to the child. These lists go beyond those recommended in the Regulations and, especially if the various policies remain separate, could potentially limit the advice and support given to women with HIV.

Conclusion

Any health policy should be accessible to government officials, health care workers and health system users. Accessibility depends not only on the clarity of the wording of the policy itself, but also on the way in which it is communicated and implemented. These Regulations should be approached with the same principles in mind.

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¹⁴ HIV and Infant Feeding: A guide for health-care managers and supervisors (WHO, 2003, p17-18)