

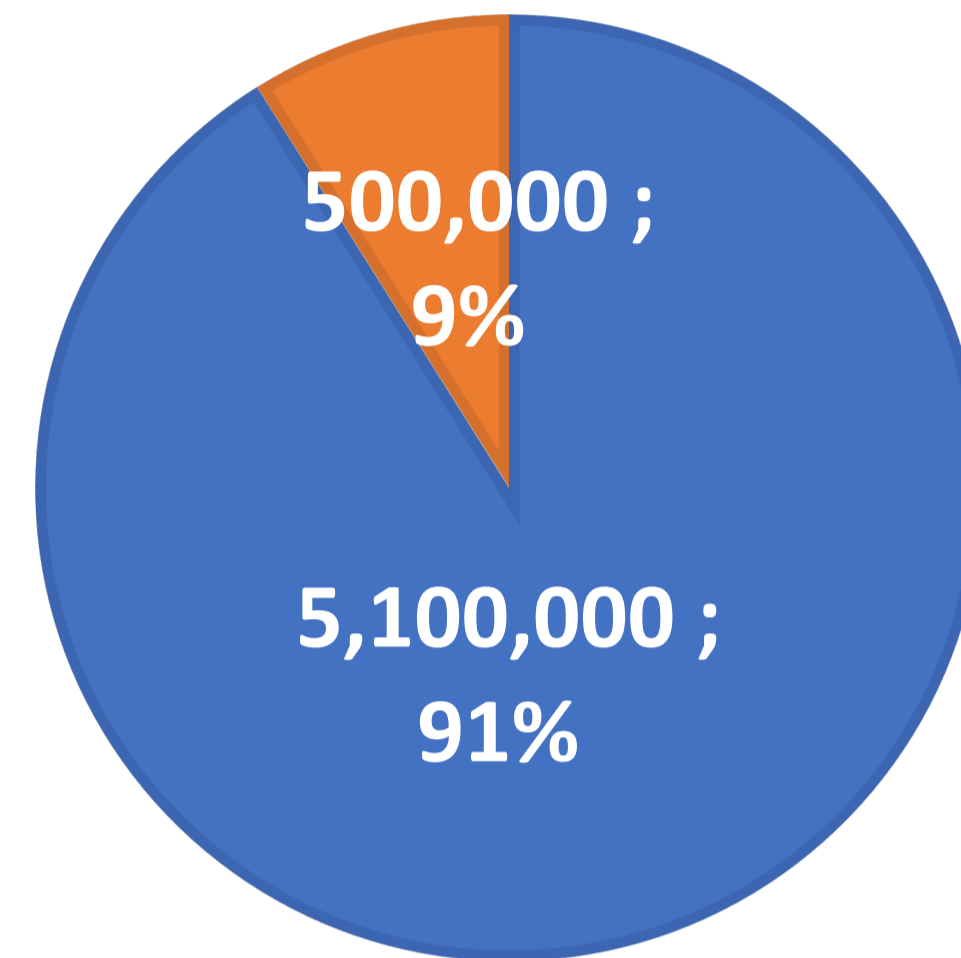
The Paradox of Sterilization for Feeding Infants: What Can We Do?

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Introduction

In Europe, 500,000 premature infants are born every year and need to be fed with artificial milk or human milk, either mother's own milk or donor milk collected by 233 Human Milk Banks.

■ Infants
■ Premature Infants



Both types of milk are defined as **FOOD** according to the current norm (Art. 2 EC n. 178/2002).

Milk can be administered in different ways: here we focus only on feeding bottles and teats.

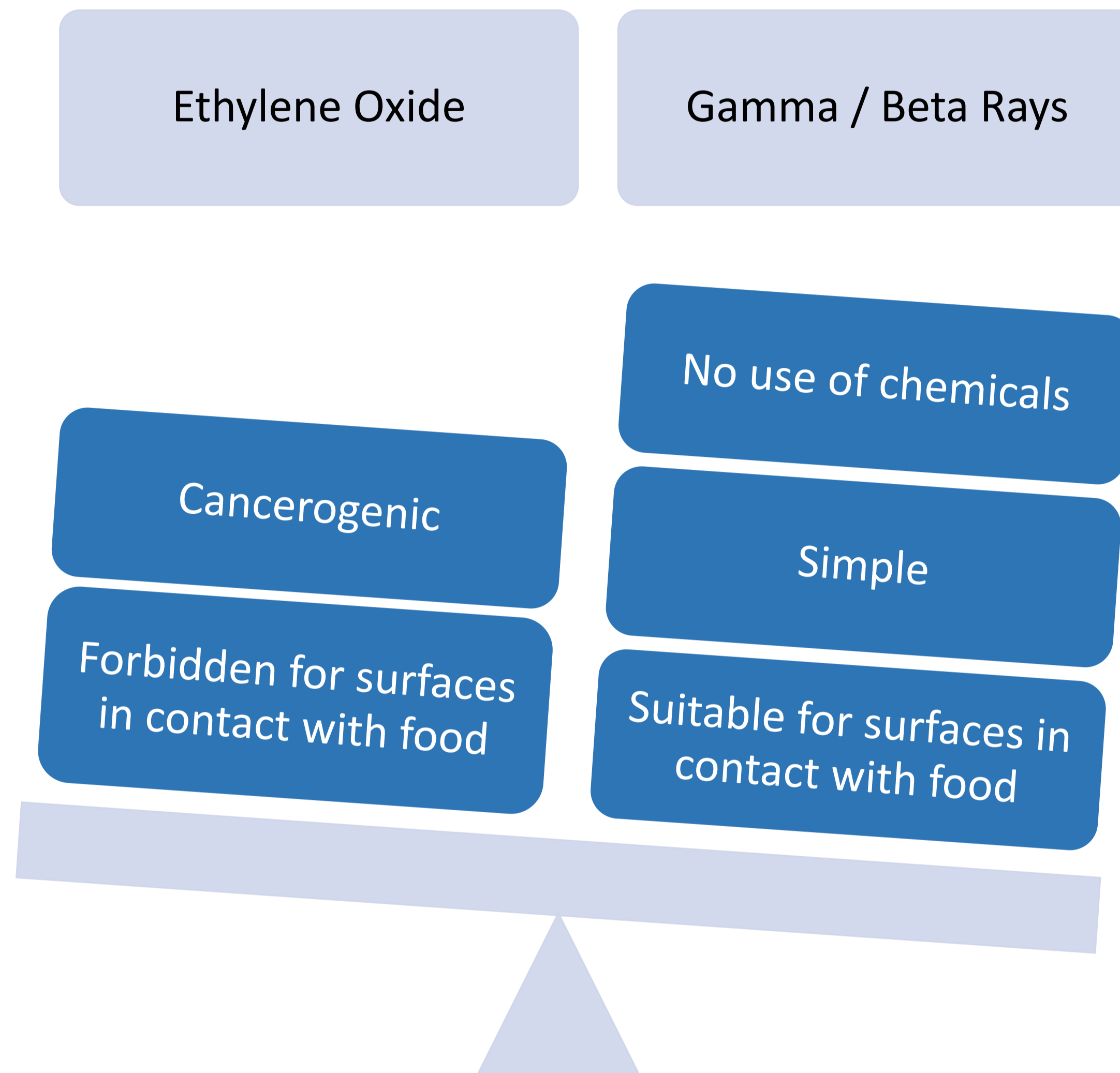
Current Norms

Different norms and regulations must be followed concerning the use of feeding bottles and teats:

- EN 14350-1:2004 : Norm on child use and care articles. Drinking equipment. General and mechanical requirements and tests.
- UE N. 10/2011 : Regulation on plastic materials and articles intended to come into contact with food .
- 93/42/CEE : Directive on medical devices, and in particular Art 7.5 *"The devices must be designed and manufactured in such a way as to **reduce to a minimum the risks posed by substances leaking from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, [...] If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer must provide a specific justification for the use of these substances with regard to compliance with the essential requirements [...]***
- 98/8/EC : Directive concerning the placing of biocidal products on the market.

Sterilization Methods

There are two main sterilization methods – with Ethylene Oxide and with Gamma or Beta Rays – which follow the norms UNI EN 5504 and UNI EN 11137-26 respectively.



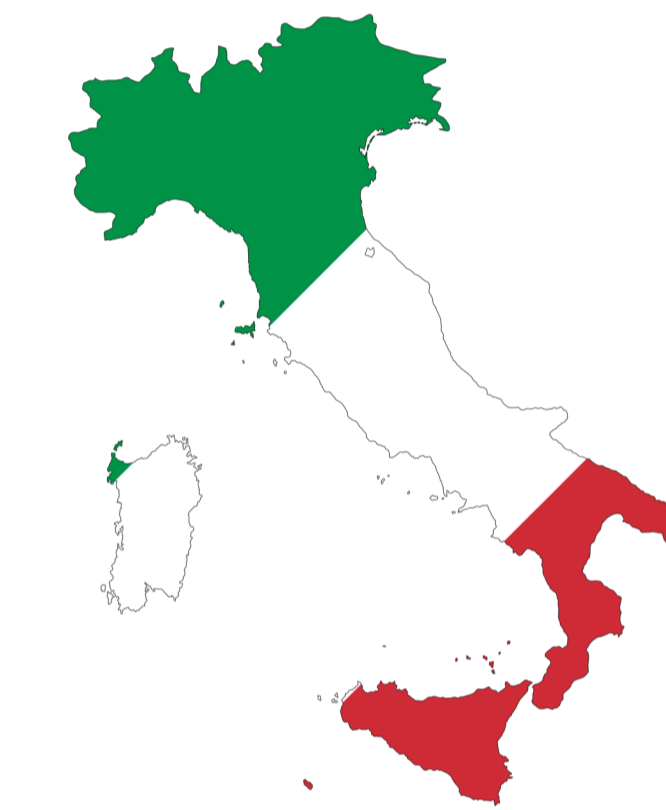
According to the EMA "Ethylene oxide sterilization should be used only where safer alternatives cannot be used."

IARC classifies Ethylene oxide as "carcinogenic to humans (Group 1)"

Country Examples

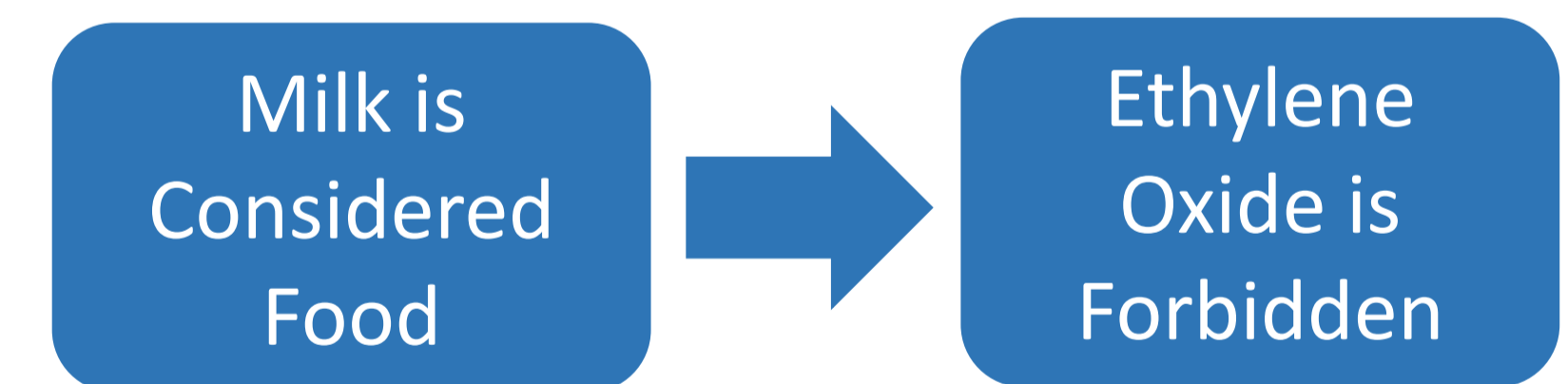


Since 2015, the French Agency for the Safety of Health Products (AFSSAPS / ANSM) suggests to avoid the use of Ethylene Oxide for sterilization of feeding bottles and teats for healthy infants, but allows its use for premature infants and for infants with severe pathologies.

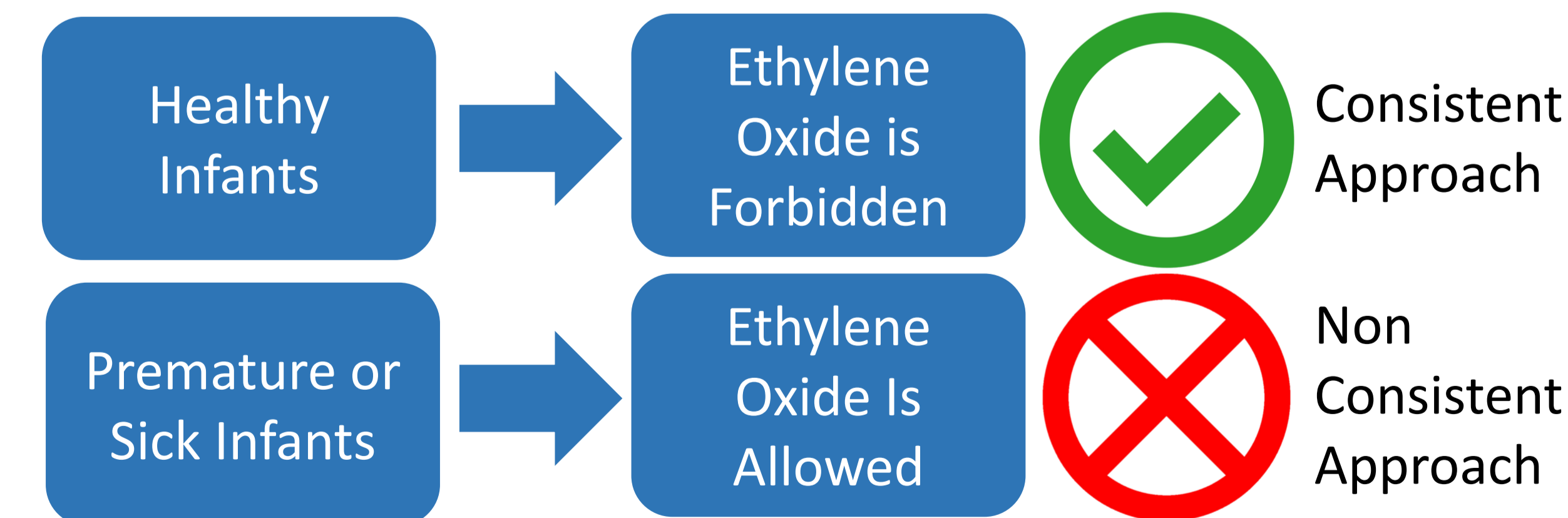


Since 2017 the Italian Ministry of Health adopts guidelines similar to the French ones.

The Paradox



How to sterilize feeding bottles and teats?



Conclusions

In this unclear and paradoxical situation, where the same products – feeding bottles and teats – can be considered either food dispenser or medical devices or something in between, and where the legislation is not 100% consistent, **protecting infants' health is becoming a matter of OUR CHOICE.**