## THE INFANT FORMULA AND FOLLOW-ON FORMULA (SCOTLAND) AMENDMENT REGULATIONS 2014 ("THE 2014 REGULATIONS")

This transposition note relates to Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC ("Directive 2006/141") as most recently amended by Commission Directive 2013/46/EU amending Directive 2006/141/EC with regard to protein requirements for infant formulae and follow-on formulae ("Directive 2013/46").

## **Background**

Directive 2006/141 was originally implemented in Scotland by the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 ("the 2007 Regulations"). The 2014 Regulations amend the 2007 Regulations and implement Directive 2006/141 as amended by Directive 2013/46.

## The 2014 Regulations

The following table demonstrates how each relevant provision of Directive 2013/46 has been given effect in the 2014 Regulations. Certain Articles of Directive 2013/46 do not need to be transposed into national law as they relate to general obligations on Member States, administrative provisions or deal with historical issues such as entry into force.

| <b>Article 2013/46</b> | in | Directive | Objective  | Implementing provision | Responsibility  |
|------------------------|----|-----------|--|------------------------|---|
| Article 1(a)           | 1, | paragraph | Amends Article 7 of Directive 2006/141 to provide for demonstration of suitability of infant formula manufactured from cows' milk or goats' milk | Regulation 2(3).       | The Scottish Ministers (on the advice of the Food Standards Agency) are responsible for all the measures taken to implement this Directive in |
|                        |    |           | proteins.  |                        | Scotland.  Applies to all subsequent entries.   |
| Article 1(b)           | 1, | paragraph | Amends Article 7 of Directive 2006/141 to provide for demonstration of suitability of follow-on formula manufactured from protein                | Regulation 2(4).       |   |

|                        | hydrolysates.      |                          |  |
|------------------------|--------------------|--------------------------|--|
| Article 1, paragraph 2 | Amends Article     | Regulation 2(5) and (6). |  |
| 71 3 1                 | 12 of Directive    |                          |  |
|                        | 2006/141 to        |                          |  |
|                        | provide for the    |                          |  |
|                        | name under         |                          |  |
|                        | which infant       |                          |  |
|                        | formulae and       |                          |  |
|                        | follow-on          |                          |  |
|                        | formulae           |                          |  |
|                        | manufactured       |                          |  |
|                        | entirely from      |                          |  |
|                        | cows' milk or      |                          |  |
|                        | goats' milk must   |                          |  |
|                        | be sold.           |                          |  |
| Article 1, paragraph 3 | Amends             | Regulation 2(2).         |  |
| and Annex              | Annexes I, II, III | 8                        |  |
| <b>6</b>               | and VI of          |                          |  |
|                        | Directive          |                          |  |
|                        | 2006/141 to        |                          |  |
|                        | enable the use of  |                          |  |
|                        | goats' milk        |                          |  |
|                        | proteins in the    |                          |  |
|                        | manufacture of     |                          |  |
|                        | infant formulae    |                          |  |
|                        | and follow-on      |                          |  |
|                        | formulae and to    |                          |  |
|                        | lower the          |                          |  |
|                        | minimum            |                          |  |
|                        | protein levels     |                          |  |
|                        | permitted in       |                          |  |
|                        | follow-on          |                          |  |
|                        | formulae           |                          |  |
|                        | manufactured       |                          |  |
|                        | from protein       |                          |  |
|                        | hydrolysates.      |                          |  |
| Article 3, paragraph 1 | Sets out the       | Regulation 1.            |  |
|                        | transposition      |                          |  |
|                        | date.              |                          |  |