Opinion: EANDCB validation

Origin: domestic

RPC reference number: RPC-3046(2)-DH Date of implementation: 6 April 2016



Foods for specific groups Department of Health

RPC rating: confirmed as low-cost regulation

Description of proposal

The proposal would implement the enforcement regime for the EU Foods for Specific Groups Regulation. The directly applicable EU regulation introduces new requirements for the composition and labelling of foods intended for certain groups for example, infant formula.

The proposed regime would also introduce a more proportionate enforcement mechanism than currently exists. This would be achieved through enabling the first formal stage of enforcement to be the issue of an improvement notice, instead of a fine.

Impacts of proposal

The main cost identified by the Department is familiarisation with the new regulations. Using industry sales data, market information, and NHS prescription data, the Department estimates that around 215 businesses manufacture products within scope of the regulations and that they will take around two hours per business to become familiar with the new improvement notices and consolidated regulations. The Department estimates the overall familiarisation costs will total around £12,000.

The Department expects that business will benefit from reduced administrative burdens on new firms entering the market, but does not consider these significant enough to monetise. The Department also expects that business will benefit from a more proportionate enforcement regime, with the use of improvement notices resulting in fewer fines. These benefits will, however, accrue to businesses that are not-compliant with existing regulatory requirements and are correctly not included in the estimated equivalent annual net direct cost to business (EANDCB).

The RPC is able to validate the EANDCB as zero, when rounded to the nearest £100,000. As the proposal introduces domestically led changes in addition to implementing the requirements, the measure is a qualifying regulatory provision for business impact target purposes.

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Quality of submission

The assessment includes sufficient information to support the validation of the Department's estimated EANDCB. The IA would, however, benefit from including some further summary information on the changes in the labelling requirements, in order to provide context for the objectives of the enforcement regime.

Initial departmental assessment

| Classification | Qualifying regulatory provision (IN) |
|--|--------------------------------------|
| Equivalent annual net direct cost to business (EANDCB) | Zero |
| Business net present value | Zero |
| Societal net present value | Zero |

RPC assessment¹

| Classification | Qualifying regulatory provision (IN) |
|-------------------------------------|--------------------------------------|
| EANDCB – RPC validated | Zero |
| Business impact target score | Zero |
| Small and micro business assessment | Not required (low cost regulation) |

Michael Gibbons CBE, Chairman

¹ For reporting purposes, the RPC validates EANDCB and BIT score figures to the nearest £100,000

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