Regulatory Policy Committee

Amending allergen provisions contained within domestic food information legislation for food prepacked for direct sale

Department for Environment, Food and Rural Affairs

RPC rating: fit for purpose

The impact assessment (IA) is now fit for purpose as a result of the Department's response to the RPC's initial review. As first submitted, the IA was not fit for purpose.

Description of proposal

The policy is intended to improve the provision of information to consumers about food allergens present in foods that are prepacked for direct sale (PPDS)[1]. The aim is to reduce the number of allergen-related incidents in which the provision of allergen information for PPDS foods is considered to be relevant. In the UK, foods other than PPDS that are prepacked are required to be labelled with full ingredients and food allergens (of which there are 14 specific allergens) in the ingredients emphasised. For PPDS products it is permitted to provide information on the presence in ingredients of the 14 food allergens in writing or orally. Anecdotal evidence suggests that it is difficult for consumers to distinguish between prepacked and PPDS foods and that they assume that the absence of allergen information means food allergens are not contained in the product (which may not be the case for PPDS foods). The Department has considered four options. Option 1 is to promote voluntary adherence to best practice, Option 2 is to require 'ask the staff' labelling on PPDS products, Option 3 is to mandate allergen labelling and the preferred Option 4 is to mandate full ingredient list and allergen labelling.

Impacts of proposal

The net present value (NPV) of the preferred option is -£321.8 million and the equivalent annual net direct cost to business (EANDCB) is £31.6 million. The Department recognises that voluntary action towards the preferred option from some

[1] The Food Standards Agency's technical guidance identified PPDS products as foods that are pre-packed on the same premises from which they are being sold (e.g. in anticipation of a customer's order).

businesses will result in noticeable changes to the NPV and EANDCB calculations. Adjusting for voluntary action from all large businesses would change the NPV for Option 4 to -£228 million and the EANDCB to £22.0 million.

Monetised costs

The familiarisation costs for the proposed measure are estimated to be £17.7 million[2]. Labelling costs are broken down into an initial transition cost and ongoing costs. The transitional labelling cost estimate is £223.67 million although the IA states this is likely to be an overestimate because some businesses are voluntarily to improving allergen and/or ingredient labelling. The estimated annual ongoing labelling cost is £13.45 million. After a two-year transitional period, there will be an enforcement cost to businesses of £0.97 million per year from additional inspections over and above the existing regime. Estimated familiarisation costs to local authorities are £1.58 million. The annual enforcement cost to the government of carrying out inspections is estimated at £1.6 million. The best estimate of the total cost of the preferred option is £321.8 million, compared to £5.2 million for option 1, £64.2 million for option 2 and £218.1 million for option 3.

Non-monetised costs

Labelling costs for small and micro supermarkets have not been monetised in the IA because the Department assumes that those businesses are not likely to sell PPDS. Introducing labelling will restrict businesses' ability to substitute ingredients without a label change. This restriction is more likely to affect smaller businesses that may substitute close alternatives for ingredients to keep costs down. The Department does not monetise this cost because it assumes that the businesses incurring this cost would be likely to switch away from PPDS products to alternatives such as loose or PCR (packed at the consumer's request) if the burden was too great. The Department has not monetised the cost of determining the full list of ingredients (there may be some cost in determining the full list of ingredients that is present in a PPDS product, particularly those containing composite ingredients like sauces), because it was unable to obtain this information through consultation and stakeholder workshops. It was not deemed proportionate to go further as most businesses already know what ingredients are in their food. The Department does not assume a specific level of pass-through of costs to consumers, and it acknowledges that if a business is unable to operate as a result of increased

[2] estimates denote the Department's central estimate.

labelling requirements, it may reduce the range of choices available to consumers. The extent of likely pass-through to customers is unknown as it is linked very closely to the rate at which businesses switch away from PPDS. Some businesses rely on the PPDS product format to meet higher demand at peak times; if they are unable to afford the new labelling costs and switch away from selling PPDS it would be possible that the output of their business may drop, due to an inability to serve as many customers in the same time frame.

Monetised benefits

The expected benefits of the preferred option are an assumed better success rate in reducing the likelihood of incidents due to allergic reactions. While the Department has monetised health benefits in an annex, it has not been able to predict the number of incidents the measure will prevent.

Non-monetised benefits

The benefits of the preferred option have not been monetised due to many of them being difficult to quantify. This difficulty appears to be due to the nature of the benefits, for example, a reduction in the number of food allergen related incidents and fatalities.

As mentioned above, the expected benefits of the preferred option are an assumed reduced likelihood of incidents due to allergic reactions. Also, as full ingredients are listed, those persons allergic to other ingredients not listed in the 14 allergens could benefit. Therefore, a further reduction in the likelihood and number of adverse reactions and fatalities from exposure to allergens is expected. The IA argues that full ingredient listing will benefit consumers with allergies as it potentially gives more choice to those who would previously have avoided unlabelled PPDS.

Quality of submission

The IA provides a breakdown of direct costs for each option considered. The Department monetises many relevant costs and explains the methodology and assumptions used to estimate them. The RPC considers the evidence in support of the EANDCB to be fairly robust and the IA has an adequate small and micro business assessment (SaMBA). The RPC considers the Department's rationale for not excluding small and micro businesses (SMBs) to be justified. However, there are several areas relating to wider impacts of the measure that should have been fully

analysed. The evidence underpinning some of the assumptions, as well as the rationale for intervention and the choice of policy option is limited.

Issues addressed following RPC's initial review

As initially submitted, the IA included several issues that meant that the RPC did not consider it fit for purpose. The initial review also highlighted further areas for improvement. In response, the Department has revised the IA. As originally submitted the assessment was not fit for purpose for the following reasons:

1. **Small and micro business assessment (SaMBA).** The RPC advised the Department that the final stage IA must clearly detail the mitigating actions that have been considered and why each particular action has not been taken. The Department has now explained what mitigations it considered and why it has not been appropriate to implement them.
2. **EANDCB.**
    a. **Rationale for intervention.** Because some businesses are already doing more than the minimum requirement, the RPC advised the Department to assess the costs and benefits against a baseline that includes voluntary action. The Department has justified the baseline used and shown in an annex the impact that a different baseline would have had on the EANDCB.
    b. **Ongoing labelling costs.** The IA did not make clear how it had obtained the unit label cost and did not mention on-going labelling costs. The Department has included its source for unit label cost and has explained that the on-going cost will be the marginal cost for each additional label.
    c. **Training costs.** The RPC was concerned that the Department had not monetised training costs in the original IA. In the revised IA the Department has drawn on evidence from its consultation to justify the assumption that there will be no additional training costs. Consultation responses state that businesses already provide training, which includes allergen training. The IA notes that many businesses make use of the Food Standards Agency's (FSA) training, especially smaller businesses which may not be able to develop their own.
    d. **Enforcement costs and costs of determining allergens.** The costs to businesses of preparing and participating in inspections had not been considered in the original IA. It did not monetise any costs of identifying allergens present in PPDS. In the resubmitted IA, the Department has estimated enforcement costs and provided an

explanation as to why they have not been able to estimate the cost of businesses determining allergens.

e. **Liability costs.** The initial IA did not discuss the potential liability consequences of a customer having an allergic reaction to a product. The Department has added detail on the likely impact of this regulation on such liability. While the Department has done enough to assure the RPC that liability will not be affected in a way that will directly affect businesses (and therefore will not affect the EANDCB), more could be done to demonstrate this in the IA.

The Department has also improved on the points identified in our initial review as Areas for Improvement:

1. **Rationale for intervention**. The Department has added further detail to support its rationale, outlining that this measure is needed to bring the regulations around PPDS foods in line with other pre-packaged foods. While the RPC is pleased to see that further justification has been added, it notes that the evidence to support the rationale for government intervention is still weak. The RPC would expect to see evidence of the market failure stated or of a cost to society that demonstrates that regulation is a proportionate and effective response.
2. **Options considered**. The Department has provided further justification as to why Option 4 was chosen despite its suboptimal cost-benefit analysis ratio. While the RPC accepts that the reasoning behind the policy decision is plausible, it notes that the evidence underpinning the decision is unconvincing. The RPC would expect the preferred option to be based on evidence, which tends to be demonstrated by the chosen option having the highest NPV.
3. **Monitoring and evaluation.** The Department has now included a section on evaluation, which states that a formal review will be carried out in autumn 2024. The Department states that this may be a light touch review because businesses would only have complied with the measure for three years (because of the two-year implementation period). The IA should provide further detail on monitoring and evaluation, such as whether or not a subsequent, more detailed review will be carried out (if the autumn 2024 review is a light touch one, for example). The RPC would expect a thorough review of this measure given the uncertainties surrounding the rationale and analysis.
4. **Comparison with other EU member states.** The Department has explained that it has not been able to compare its proposal with the effectiveness of

different measures in other countries because those measures have not been implemented for a sufficient period of time.

5. **Indirect costs associated with new labelling.** The Department has added a short paragraph acknowledging that competition between suppliers could be affected. However, the Department does not estimate the scale of this impact or explain why it has not been able to do so.
6. **Costs to consumers.** The Department has now recognised in the IA that consumer choice could be reduced if some businesses (particularly SMBs) are no longer able to operate. However, the Department states that the scale of this impact is unknown because it depends on the extent to which businesses may be able to switch away from PPDS foods (as opposed to ceasing operations).
7. **Missing wider costs and risks of the policy – businesses taking a cautious approach.** The Department has added a paragraph stating that it has assumed that precautionary labelling is unlikely to increase as a result of this measure. However, the Department does not go into detail about how certain this assumption is and what the consequences would be if some businesses do take a cautious approach.

While the Department has amended most of the points identified as areas for improvement, the IA would be strengthened by further development in many of these areas. As there are several uncertainties in the analysis and there are likely to be high costs to businesses relative to any benefits, the Department must commit to a more detailed monitoring and evaluation plan. The information needed to measure the direct, indirect and wider impacts of this measure must be collected once the proposal has been implemented in order to inform a full post-implementation review (PIR). In particular, the Department should aim to capture changes in sales, causes and costs of allergen-related incidents, data on the content of labelling and changes in supply arrangements (especially for SMBs).

The Department does not assess the risk that the measure could distort market outcomes, for example by discouraging businesses from using potentially more effective solutions; the IA would benefit from further discussion of this risk. The IA would also benefit from a stronger explanation as to why the Department believes that businesses are unlikely to take a cautious approach and list more ingredients (particularly allergens) than are actually in a product, in order to keep labelling costs down should they wish to change suppliers or ingredients. If businesses took that approach, it could reduce consumers' choice and/or their faith in the labelling system. This is important to understanding whether or not the objectives of the policy are likely to be achieved. The Department should have more explicitly considered

the impact on businesses that sell food PPDS as a side-line, such as garden centres and visitor attractions. The IA should also have considered how the cost burdens will affect the PPDS market overall, as profit margins will fall relative to other foods. The IA would also have benefitted from a more convincing account as to why liability costs are not likely to be affected by this measure.

In the final IA, the Department acknowledges some wider costs but does not support these with evidence. The proportion and kinds of businesses that switch away from PPDS should have been thoroughly analysed, and the IA should include an estimate of the indirect impact of this switch on the suppliers of packaging. The Department could have drawn on consultation evidence to demonstrate that this measure will affect competition among ingredients suppliers, as sellers of PPDS products may be more likely to stick with an existing supplier rather than use a new supplier offering alternative ingredients in order to keep labelling costs down. This could also inhibit innovation in the search for better and safer alternatives to existing ingredients.

Departmental assessment

Classification	Qualifying regulatory provision (IN)
Equivalent annual net direct cost to business (EANDCB)	£31.0 million (initial estimate) £31.6 million (final estimate)
Business net present value	-£272.2 million
Overall net present value	-£321.8 million

RPC assessment

Classification	Qualifying regulatory provision (IN)
EANDCB – RPC validated[3]	£31.6 million
Business Impact Target (BIT) Score[1]	£158.1 million
Small and micro business assessment	Sufficient
RPC rating (of initial submission)	Not fit for purpose

Regulatory Policy Committee

[3] For reporting purposes, the RPC validates EANDCB and BIT score figures to the nearest £100,000.