



The role of socio-economic analysis in compiling an application for authorisation: A practitioner's view

Richard Dubourg

The Economics Interface Limited

richard.dubourg@theeconomicsinterface.com

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Why am I here?

- Over last two years, contributed to around a dozen applications for authorisation – one of the lead authors on eight applications
- (Seven out of 12 documents on the ECHA ‘examples’ website were co-authored by TEI (me))
- Before that, spent two years at ECHA, as coordinator for SEA, and involved in the design of many aspects of the authorisation process
- Applied economist with 25 years’ experience, including seven in academia
- Non-market valuation, cost-benefit analysis, environmental economics etc

My approach to SEA in AfAs

- SEA thinking integrated into both the AoA and the CSR
- The core SEA ‘drops out’ of these two – a few adjustments and additions to make a full SEA
- Leads to a clear and focused ‘narrative’ through the entire AfA; transparent analysis, evidence-based argumentation
- *‘How we envisaged it’*
- SEA itself is quite slim – all the work is done in the AoA (and CSR)

Integrating SEA into the AoA

- The AoA as an options appraisal, from the applicant's perspective, with the objective of identifying the non-use scenario
- This objective means appraisal must include technically *practicable* options – including 'managerial' options (e.g. relocation, closure)
- Assessment of technical feasibility can include exploration of what would be required to make an option technically feasible (inc. timescales and cost) – R&D plan
- Least-cost (or 'most likely') practicable option becomes the non-use scenario
- 'Suitability assessment' is secondary

The 'standalone' AoA

- AoA set up to demonstrate non-suitability, with focus (exclusively?) on 'technical' (i.e. non-managerial) alternatives
- Focus also on 'static' technical feasibility – costings often vague
- Conclusion: 'There are no alternatives'
- Non-use scenario identified separately, 'out of nowhere'
- Non-use scenario not clearly least-cost, or best alternative for applicant, or even actually likely to be adopted if use must stop
- 'Suspicion' that AoA and non-use scenario designed to justify AfA – biased analysis

Integrating SEA into the health impacts assessment

- Made significantly simpler by having cancer endpoints and RAC dose-response functions. (*Much* more difficult for other endpoints and environmental impacts)
- Permits standardised approach to linking exposures and risks in the CSR (via spreadsheet) to costs (per year) of additional cancer risk
- Variables: Exposures, populations at risk, dose-response coefficients and timeframe, (national) cancer survival rates
- Fixed: Costs of fatal and non-fatal cancer
- Annual, best-estimate costs, not (e.g.) ‘worst case over 70 years’

Employment (and other impacts)

- Standardised approach based on administrative data sources and application-specific data where available and useful
- Unemployment treated as temporary – core impact is temporary loss of output. (Other impacts now included, e.g. ‘scarring’)
- Evidence (e.g. Eurostat) suggests average unemployment shorter than two years – limits importance in benefit-risks comparison
- Other AfAs treat unemployment as permanent – not supported by evidence, and greatly exaggerates costs
- Other impacts – largely distributional (e.g. competition) rather than affecting net benefits; treated qualitatively

The importance of the ‘application strategy’

- Integrated approach requires SEA thinking to be present from the start
- ‘Application strategy’ drawn up immediately following initial discussions and site visit
- Sets out basic understanding of the issues, information needs, initial argumentation and assessment of strength (including rejection)
- Used to challenge client and application team; (even used six page strategy document for PSIS discussion)
- The earlier and better we can set out the application strategy, the easier is the development of the AfA and the better is the ultimate presentation of the case

Difficulties and weaknesses

- Geographical scope, e.g. treatment of costs of relocating outside of the EU, value-added, risks – applicants and SEAC inconsistent
- Capital redundancy – with closure, capital is not necessarily lost (completely) and will be re-employed; our current approach (based on scrap/secondhand market values) seems adequate, others assume profit loss is permanent
- Confidentiality (etc), e.g. information about alternatives is business-critical and strategic (e.g. reveals ability to pay higher prices) and will (can?) not be shared within supply chains
- Upstream applications – what quality of information is acceptable? How to achieve a realistic non-use scenario?

Effect of the ‘integrated approach’ and SEA (I)

- All AfAs submitted following this approach positively received; supportive opinions with positive comments and a long (or requested) review period
- AfAs tightly focussed with a clear narrative, analytical approach and assumptions; saves resources and allows focus on what really counts – exposures and the AoA
- Risks in all (our) cases very (vanishingly) low (and some clients have spent significant sums getting them even lower) – no question of whether these AfAs granted, so SEA little ‘role’ to play
- Risk minimisation, additional measures etc not based on SEA; RAC and SEA views on what counts as low risk not consistent

Effect of the ‘integrated approach’ and SEA (2)

- Review periods: Very low risks, high non-use costs, very long lead times, indicate (based on SEA) longer than 12 years, but argumentation not clearly accepted by SEAC; Commission?
- Not clear ‘better quality’ AfAs necessarily get better outcomes; Lot of interpretation and interpolation by SEAC of content of poor AfAs, which has compensated for their poor quality
- Quality-review period tradeoff – Need to distinguish between good AfAs with good or poor information, and poor AfAs, e.g. through review period (including ‘provisional’ authorisation)
- SEA makes explicit the values and tradeoffs in a decision – not explicit for (e.g.) additional measures, ‘unacceptable risks’ etc



Thank you

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