

Recommendation	support	Do not support	Comments, enhancement needed
<p><b>1. Structure, organization and operation of the federal food regulatory system</b></p> <p>1.1 measures to ensure clear separation of the gov't's regulatory role from other roles</p> <p>1.2 clear description of regulatory procedure &amp; protocol</p> <p>1.5 accurate communication regarding the operations of the regulatory committee</p> <p>1.3 establishment of a Ruling Committee</p> <p>1.4 regular reviews of regulatory bodies by the auditor general</p> <p>1.6 "Efficiency and effectiveness"</p> <p>"Periodic" review of regulatory capacity</p> <p>Coordination of monitoring &amp; surveillance to detect potential long-term and environmental effects</p> <p>1.7 spokesperson and coordinator of communications re gov't policies = "senior authoritative officer responsible for regulation of novel foods"</p> <p>1.8 model for organizational options for 1.6 and 1.7</p>	<p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p>		<p>How does 1.5 differ from 1.2?</p> <p>Who is on the ruling committee? What authority does it have?</p> <p>Efficiency &amp; effectiveness for whom? -for the biotech developers? regulators? public? Should be far more often than 10 years. New and more complex products are being researched all the time.</p> <p>why?</p> <p>Not sure if coordination of existing bodies is better than new agency...</p>

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<p><b>2. Transparency</b></p> <p>2.1 ...that the regulatory process provide for significantly expanded opportunities for input by the public and external experts</p> <p>2.2 Canadian public &amp; external experts involved in public policy re health, environment, social &amp; ethical issues</p> <p>2.3 comment period – 45 days – on “proposed decisions”</p> <p>2.4 policy that developers’ data does not automatically fall under CBI, and amend Access to Information Act to make info more available</p> <p>2.5 unusual or unprecedented cases – get external viewpoint</p> <p>2.6 communication re regulatory decision process</p> <p>2.7 information on products currently under review</p> <p>2.8 “information” on <i>contained</i> field trials – annually</p> <p>2.9 “information” on research programs &amp; results – annually</p> <p>2.10 more information to growers re field study locations</p>	<p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p> <p>X</p>		<p>acceptability spectrum is one option</p> <p>Comment at what stage of development? What decisions?</p> <p>Need criteria, possible examples, protocol here</p> <p>Similar to 1.2 and 1.5</p> <p>Support, if actual products revealed</p> <p>Information on what else besides compliance or non-compliance? This will likely be mostly reassuring information – might be of limited use</p> <p>Should include the amount of government spending and corporate investment into biotech research. Should also include how much resources are allocated to alternative solutions to agricultural concerns such as pest management or nutrient alterations</p> <p>Locations should be given to all growers close to the locations, not just “on request”</p>

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<b>3. Precautionary Elements</b>			
3.1 strengthen regulatory oversight to novel foods and plants, not just product of technology	X		Need clear distinction between “precautionary principle” and “precautionary approach” – e.g. 2 <sup>nd</sup> bullet under 3.3 – state this up front
3.2 “conservative” safety standards in assessing health and environmental risks			
3.3 Precautionary <i>approach</i>			Define “catastrophic harm”, define “conservative standard”; explain how “potential severity of risk” is determined; be clear about how “benefits” are measured.
Estimate potential costs of actions or lack of actions	X		Have estimates done by academic experts with expertise in ecology and health science, not KPMG)
Precautionary measures subject to reconsideration	X		Who will be involved in such reconsideration?
“Where 2 or more “equally effective” options are available to mitigate risks, the least trade-restrictive option should be given serious consideration”.			Who determines if options are “equally effective”?
3.4 study how effectively existing guidelines are being applied and enforced	X		Very concerned that this is not currently being done
3.5 government initiated funding for GM research			
-analytical methods	X		Should be matched by research into non-GM opportunities & knowledge
-knowledge base			More frequently than every 10 years.
3.6 post-market review of products	X		More frequently than every 10 years, and should include assessment methodologies
-reassessment possible	X		
3.7 reviews of regulatory regime - protocol, science, resources, international cooperation	X		
3.8 regulatory process = “efficient, timely, assist small/medium development enterprises”, “without compromising effectiveness”			This looks like strong federal support for biotech industry with taxpayers’ dollars. Is non-GM research being funded too?
3.9 Substantial equivalence continues as “guide”		X	SS tends to act as guide for lack of need for assessment, rather than the reverse; i.e. the opposite of precautionary approach.
3.10 revise definition of “novel trait” to exclude substantial equivalence – less ambiguous	X		

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<b>4. Evaluation and monitoring of long-term health impacts</b>			
4.1 “major long-term research program” re hypotheses on long-term health effects	X		
4.2 improve food consumption data collection	X		
4.3 incorporate above into -?- (unclear) and review approvals of <i>existing</i> products based on <i>post-market</i> data		X	This data needs to be considered at the pre-approval regulatory stage, before being incorporated into the food system

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<b>5. Environmental stewardship</b>			
5.1 government establish continuing programs of research	X		Tax-payers’ dollars should also be allocated to preservation of environment – not just impact of hazards
5.2 management of health & environmental risks -isolation zones			Specify limitation of effectiveness of zones, and compliance
<b>-traceability – requirement prior to authorization of confined field trials</b>	X		
-audit programs for effectiveness and compliance	X		Will require resources
5.3 feasibility study within 1 year re global research collaboration <i>needs</i> “making <i>wider use of</i> ecological expertise within risk assessment process”	X		Explain “wider use of” such expertise – how much wider? Also: when research collaboration needs identified, follow up with actual research
Independent panel to review & recommend ecologically meaningful protocols, standards, indicators	X		

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<b>6. Information &amp; Consumer Choice</b>			
6.1 gov't allocate additional resources so that consumers can make informed choices and get accurate and comprehensive information	X		<b>how? and by whom?</b> <b>Collaboration with public health?</b>
6.2 centralized food information service as primary venue for information dissemination		X	...even if integrated between various parts of gov't – does not enhance consumer trust)
6.3 reliable information to be developed <i>for</i> health care professionals & other intermediates	X		Support, but this should be done <i>with</i> such professionals, not <i>for</i>

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<b>7. Labelling</b>			
7.1 voluntary labelling system with clear criteria and verifiable statements		X	This would not work
7.2 review of system every 5 years; if it does not work, consider mandatory labelling	X		
7.3 voluntary system be widely promulgated and promoted	X		Support but question effectiveness
7.4 harmonized approach to labelling with other countries		X	This simply means compliance with whatever the Americans promote, and might mean pressure on EU, Japan and African nations who want mandatory labelling to change their policies)
<b>8. Other social and ethical considerations related to GM foods</b>			
8.1 continue with development of the Acceptability Spectrum	X		
8.2 gov't increase capacity of developing countries to protect their tradition knowledge & resources	X		
8.3 CIDA program use modern biotechnology (MB) where appropriate			Caution: who decides if it is “appropriate” to improve health or agriculture?
Strengthen regulatory processes to protect against risks of MB in other countries – work with NGOs and UN			Should specify: use only with countries who decide to accept MB – should respect such countries' rights to refuse MB if they wish