Specific FF/MC and ENV needs for selection of comparators

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GMO Panel

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	Definitions of approach		*Comment*
MC / FF	EC 1829/2003: Comparator is a *"similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use"*	Codex: A conventional counterpart is a *"related organism / variety...., for which there is experience of establishing safety based on common use as food"*	Establishment of *well-understood baselines* for food safety based on human consumption over 10000 years of farming
ERA	2001/18/EC: the following general principles should be followed when performing the ERA: *"identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organisms from which it is derived and its use under corresponding situations".* ..... *"Information from releases of similar organism and organisms with similar traits and their interaction with similar environments can assist the ERA".*	OECD (1993) *"Familiarity plays an important role in safety analysis, [but] is not synonymous with safety. Familiarity with the environment comes from knowledge of both ... managed [agriculture] ... and natural wild surroundings."*	All agriculture has an adverse effect on the environment – therefore: no history of safe use No well-defined baselines exist Adverse effects of conventional agriculture are dynamic

Example from UK's Farm-Scale Evaluations

1999	UK Farm-Scale Evaluations of GMHT crops begins. Three-year study of wildlife in three crops: OSR, sugar beet, fodder maize
3 October 2003	EU announces ban on herbicide atrazine – key component of weed control in *conventional* maize
28 October 2003	FSE results published. GMHT management gives adverse effects for OSR and sugar beet, but *positive* effects for fodder maize. Controversy over whether positive effects for maize would still be found had conventional management *not* included atrazine.
2 April 2004	UK Advisory Committee on Releases to the Environment (ACRE): "In the future a different herbicide regime will replace the use of atrazine ... on conventional maize, which ***raises issues concerning the interpretation*** of the maize results from the FSEs."

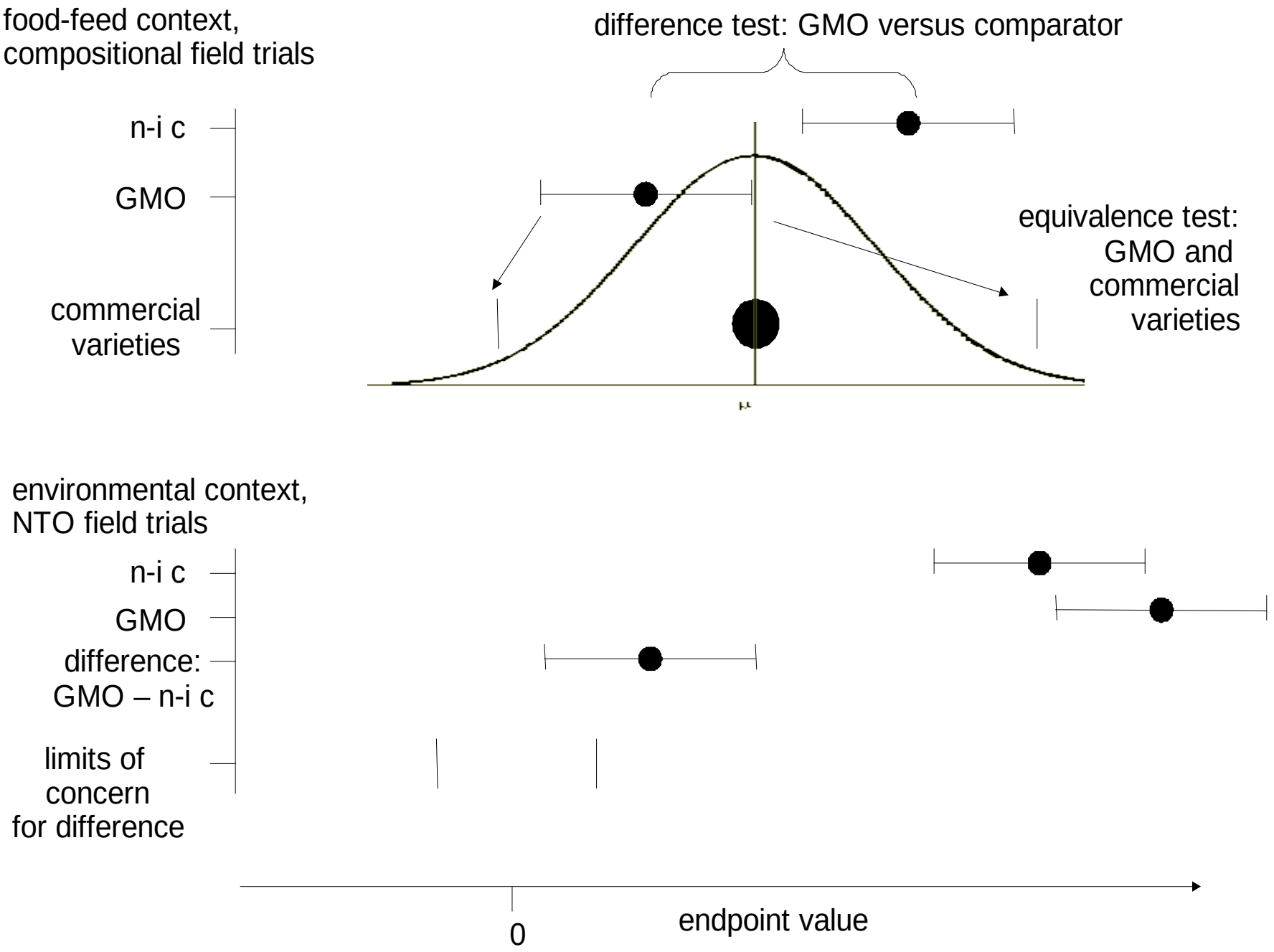
Problem caused by lack of fixed, objective baseline against which to compare GMHT; agricultural management regimes change temporally - conventional comparators are dynamic

MC/FF and ERA – differences in field experimental design

	Field plots	*Replication*	*Treatments*	*Questions addressed*
MC/ FF	small (e.g. 25m^2)	adequate	can compare several	Few types of field trial.
ERA	large (e.g. 1000m^2)	often restricted	usually two	Many types of field trial for different purposes

MC/FF and ERA – differences in equivalence testing

	Principle	*Equivalence limits*
MC/ FF	History of safe use gives range for any endpoint	Range estimated by conventional reference varieties in experiment
ERA	Protection goals used to set 'limits of concern' that indicate significant adverse effect	Identified with 'limits of concern' – *at lower tiers:* triggers for further study *at higher tiers:* reflect actual harm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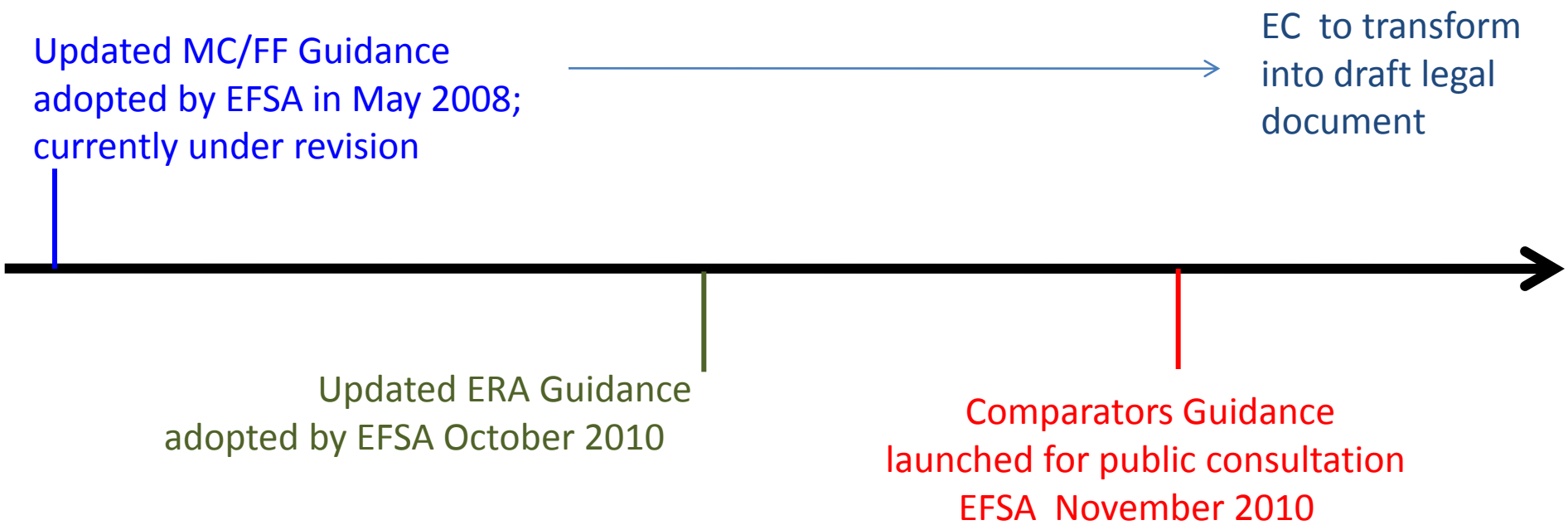
Integration of Guidance on MC/FF, ERA & Comparators



Comparators Guidance

General text

Text specific to MC/FF

Text specific to ERA.

ERA *always* uses non-GM as comparator.

Uses conventional counterpart in great majority of cases