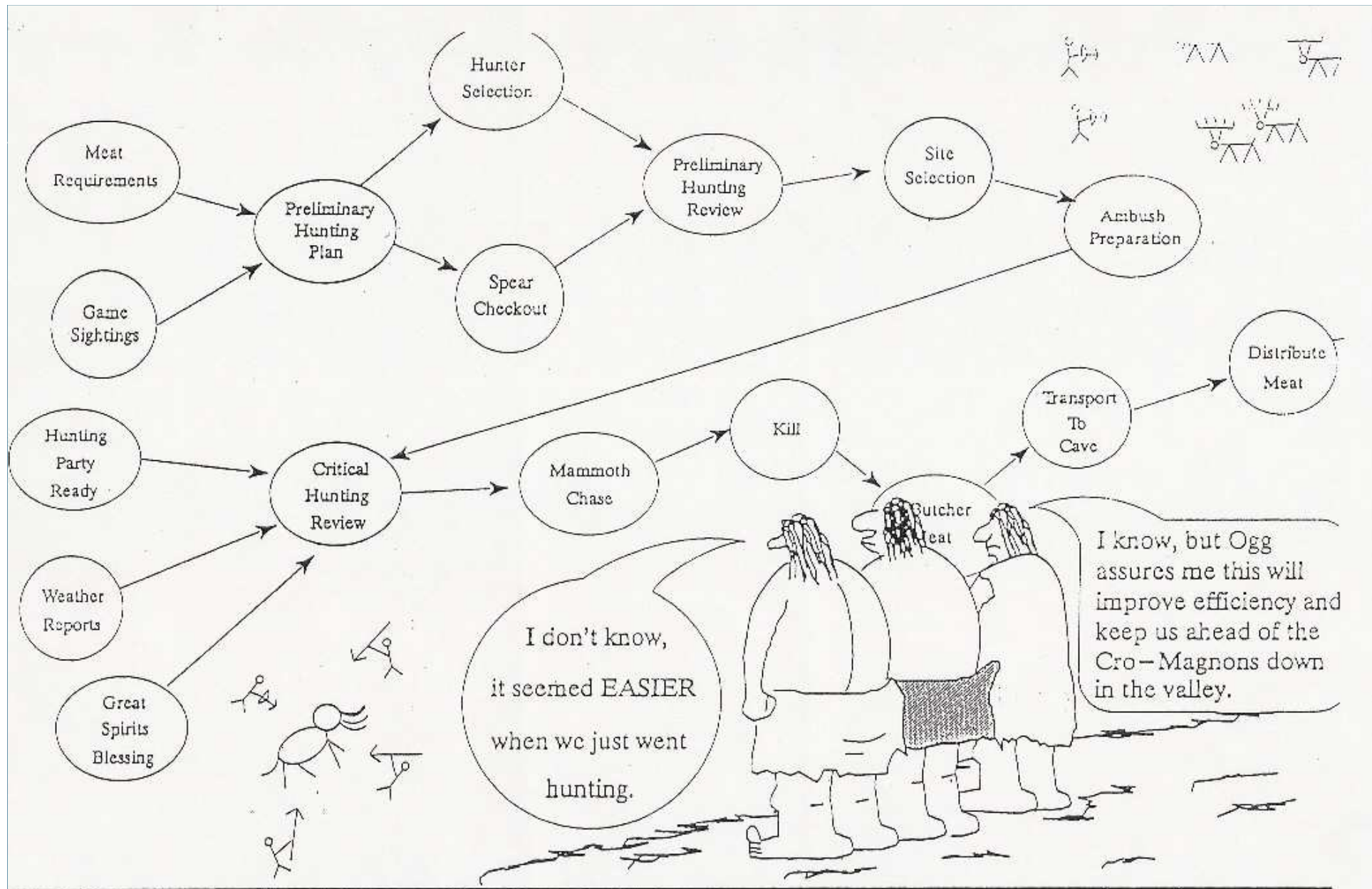


PGR Data Quality Management

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Quality Management Systems

Theo van Hintum
GCP Workshop on Passport Data Quality
July 3rd, 2007



WHY NEANDERTHAL MAN BECAME EXTINCT.

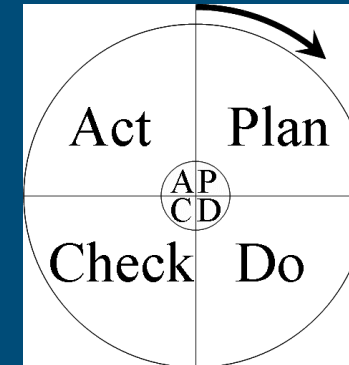
Quality Management Systems

- PGR data quality management
 - measures to assure, maintain and increase the quality of PGR data
 - PGR data is more than passport data
 - focus of this workshop is on passport data
- quality management systems are well established
 - applied in some genebanks
 - completely unknown in others
 - focus of this presentation

Quality Management Systems

■ principles of quality improvement

- Shewhart cycle
- plan
 - establish the objectives and processes necessary to deliver results in accordance with the specifications
- do
 - implement the processes
- check
 - monitor and evaluate the processes and results against objectives and specifications and report the outcome
- act
 - apply actions to the outcome for necessary improvement



Quality Management Systems

- Quality Management System (QMS)
 - formalized system that documents the organization, responsibilities and procedures required to achieve maximum effectiveness at the lowest overall cost to the organization
 - integrates the various internal processes within the organization
 - provides a process approach for project execution
 - enables identification, measurement, control and improvement of core business processes

Quality Management Systems

- principles QM
 - say what you do
 - write a quality manual
 - do what you say
 - follow the procedures in the manual – or change the manual
 - let someone check
 - an independent actor (such as a certifying agency)

Quality Management Systems

■ example CGN

- adopted a Quality Management System according to ISO9001:2000
- most of its operations have been certified since December 2004 by RWTÜV, a major German certification body
 - first genebank with formal certification
- now IPK is certified as well, others are working on it
 - GPG2 and GCP are pushing the concept

Quality Management Systems

■ example CGN

- CGN Quality Manual consists of chapters on a/o
 - general management (policy, strategy, budget, project execution, etc.)
 - organization and staff (responsibilities, expertise, training, etc.)
 - measurement, analysis and improvement (specifying how the processes are monitored, how complaints are handled, and improvements are made)
 - sector specific parts describing all technical operations
 - acquisition of material
 - multiplication (with crop specific regeneration protocols)
 - seed management

Quality Management Systems

■ example CGN

● advantages

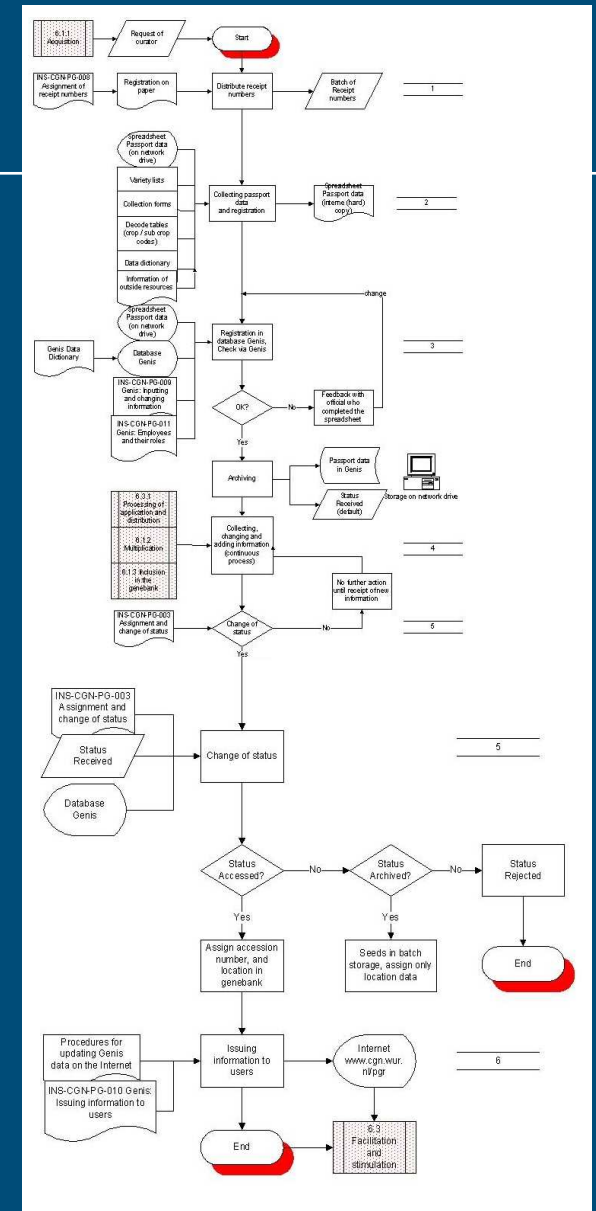
- procedures can be discussed and improved where appropriate
 - in the process of creating the Quality Manual, we identified many gaps where no internal rules have been discussed or agreed, and no shared awareness on practices exist
- new staff can easier be introduced in the procedures, and guests and colleagues can easily find out how things are done and organized
- funding agencies and external collaborators have guaranties for the quality of the genebank
 - CGN's main funding agency, the Ministry of Agriculture, Nature and Food Quality required an externally certified quality system

Quality Management Systems

■ example CGN

● documentation components CGN-QMS

- relatively simple description
- included processes
 - assignment of receipt numbers
 - collection of passport data
 - registration in GENIS
 - adding and changing information
 - changing accession status
 - providing information via internet
- result: no mess



Quality Management Systems

■ example CGN

● indicators effectiveness documentation

- bi-annual test of restore back-up has to be 100%
- internal consistency (keys, formats, etc) has to be 100% - measured with script
- supplied information has to be entered in the system within 14 days, periodically measured by comparing date supply with date acceptance input (both digitally available)
- Genis has to be at least 98% of the time on-line, analysed using the WUR-CMS data
- quality website is evaluated by panel of 3 users annually using questionnaire and interview

Quality Management Systems

■ example CGN

● feedback

- feedback is requested whenever possible
 - pro-active approach
- all written feedback is formally treated
 - discussion with process owner
 - report about handling
- feedback is considered the best way to improve quality
 - not only in a genebank

Quality Management Systems

■ example CGN

- additional IS certification for CGN documentation system
 - developed for Alterra Data and Models
 - predictions for environmental effects
 - CGN test case for suitability adoption in Plant Research International
 - certified early 2006

Quality Management Systems

- example CGN
 - elements IS certification
 - theory
 - technical documentation
 - user documentation
 - tests & validation
 - management and exploitation plan

Quality Management Systems

■ conclusions

- QMS provides tool for maintenance and improvement of quality
- impact on passport data quality is limited