Ⅳ セミナー

Seminarの実施について

- 場　所　Mongolian national chamber of commerce & Industry 大会議室
- 議　長　General Secretary of chamer of commers Enebish OYUNTEGSH
- 通　訳　Suuri Myagmarsuren
  Bayar Bujimaa
- プログラム　別紙

講演Ⅰ

Mongolian Food Industry Association EXECUTIVE Director h.DAMDINSUREN, DrSo.

①農畜産物の消費，供給状態

②食品衛生法，HACCP，ISOの実情，輸出入の衛生検査実態，栄養実態

③食品保存，伝統的製品，健康食品，肉加工法の問題，未殺菌乳販売

講演Ⅱ　櫻井勇平　HACCP

講演Ⅲ　阿部範雄　ISO

講演Ⅳ　小林敏孝　モンゴル乳業に関する私見

**ХҮНСНИЙ БҮТЭЭГДЭХҮҮНИЙ ХАДГАЛАЛТ ХАМГААЛАЛТ,
ЧАНАРЫН ХЯНАЛТ (HACCP, ISO 9000) СЭДЭВТ
СЕМИНАРЫН ХӨТӨЛБӨР**

10-р сарын 30

09.30-10.00	Бүртгэл

Танилцуулга

10.00-10.10	Нээлт, МҮХАҮТ-ын дарга С. Дэмбэрэл
10.10-10.30	"Монгол улсын хүнсний аюулгүй байдлын тулгамдсан зорилтууд" - Монголын Хүнсчдийн Холбооны Гүйцэтгэх Захирал, доктор Л. Дамдинсүрэн

***Эрүүл ахуйн эгзэгтэй цэгийн хяналт (Hazard Analysis & Critical Control Point)
(HACCP эксперт, инженер Юхей Сакурай)***

10.30-11.30	Эрүүл ахуйн эгзэгтэй цэгийн хяналтын систем
11.30-11.45	Завсарлага
11.45-12.00	Асуулт хариулт

***Чанарын удирдлагын олон улсын стандарт (ISO 9000)
(Япон улсын хөлдөөсөн бүтээгдэхүүнийг магадлан шалгах байгууллагын
Ерөнхий Менежер Норио Абе)***

12.00-13.00	Чанарын удирдлагын олон улсын систем (ISO 9000)
13.00-14.00	Өдрийн зоог

***Сүү сүүн бүтээгдэхүүн үйлдвэрлэгчдийн өнөөгийн байдал
(Сүүний үйлдвэрийн технологч Кобаяши Тошитака)***

14.00-14.30	Монгол улсын сүү сүүн бүтээгдэхүүн үйлдвэрлэгчдийн өнөөгийн байдал
14.30-15.30	Ферментжүүлсэн бүтээгдэхүүнийг хөгжүүлэх
15.30-15.45	Завсарлага
15.45-16.00	Асуулт хариулт
16.15-17.30	Хүлээн авалт (Бишрэлт зочид буудал)

講演Ⅰ　Mongollion Food Industry Association
Executuie dlirector h. DAMDINSUREN, DrSO

テキスト１

1. モンゴルの食糧備蓄

家畜数（百万頭） うち:　-雌 　　-子供の家畜	 24,0-30,0 12,0-14,0 9,0-11,0
年間食肉生産 総重量（千トン）	 230,0-300,0
年間乳生産（百万リットル）	 500,0-600,0
農地面積（１千ヘクタール） うち:　-牧草地 　　-輪作耕地 年間作付面積 うち:　-穀物 　　-ジャガイモ 　　-野菜	126000,0 124000,0 1340,0 800,0 600,0 11,0 3,0
年間収穫高（千トン） 　　-穀物 　　-小麦 　　-ジャガイモ 　　-野菜	 600,0 400,0 130,0 50,0
飲料水（立方キロ）	34000,0

2. 主要食糧の生産と需要

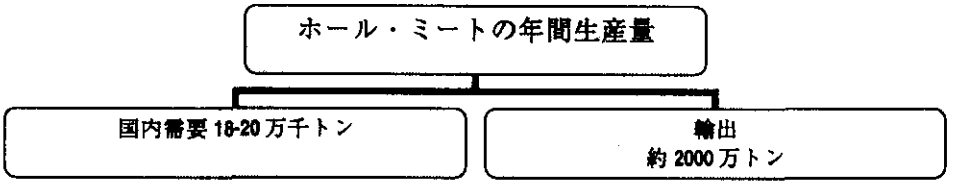
食糧	単位	年間生産量	年間需要量	増減 (+;-)
肉	千トン	226,4	180,0	+46,4
乳	百万リットル	290,3	297,4	+7,1
穀物 うち小麦	千リットル	142,2 138,7	370,0 350,0	-227,8 -211,3
ジャガイモ	千リットル	58,0	90,0	-32,0
野菜	千リットル	44,5	150,0	-105,5
卵	百万個	7,7	25,6	-17,9

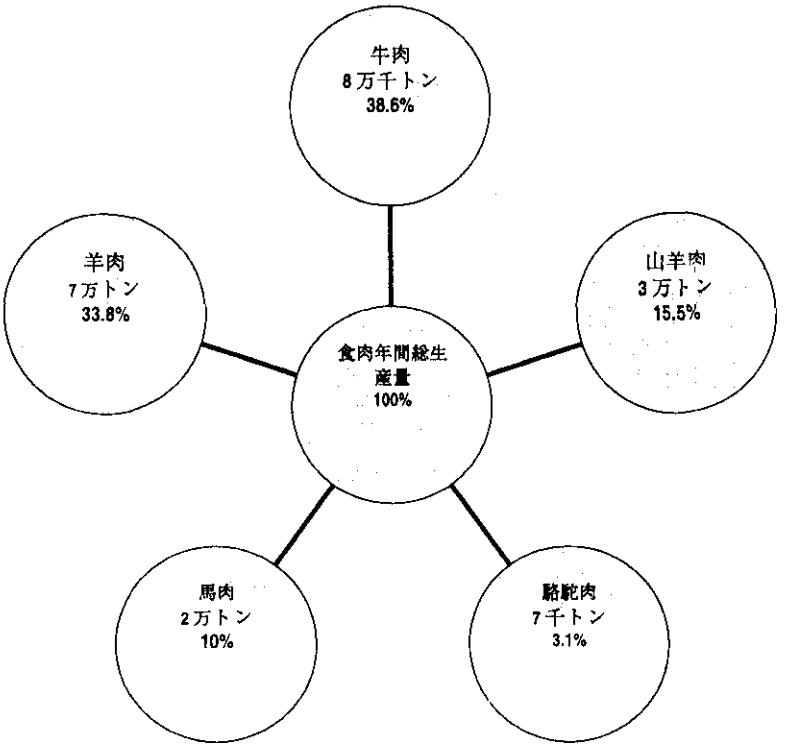
3. 主要食糧の需要

(加重平均, 重量, キロ)

品目	推奨	1990	1995	1999	2000	2001	2002
肉・同製品	84,0	97,0	96,7	112,8	120,0	97,2	120,0
乳・同製品	198,7	118,0	125,5	146,4	130,8	100,8	130,8
バター	9,8	3,0	4,2	2,4	2,4	2,4	2,4
小麦・小麦粉・同製品	124,1	97,0	94,3	99,6	108,0	110,4	108,0
米	16,4				14,4	15,6	14,4
砂糖・甘味料	21,9	23,0	8,7	8,4	10,8	12,0	10,8
魚・同製品	3,1	1,0	0,7	0,00	0,00	2,4	0,00
卵	85,0	29,0	2,5	3,6	8,4	14,4	8,4
ジャガイモ	43,8	23,0	11,3	16,8	21,6	26,4	21,6
野菜	73,0	20,0	7,9	12,0	12,0	16,8	12,0
果物	102,2	9,0	0,3	2,4	3,6	3,6	3,6
植物油	9,1	1,0	0,9	4,8	6,0	6,0	2,4

図表 2. 肉の生産と分類

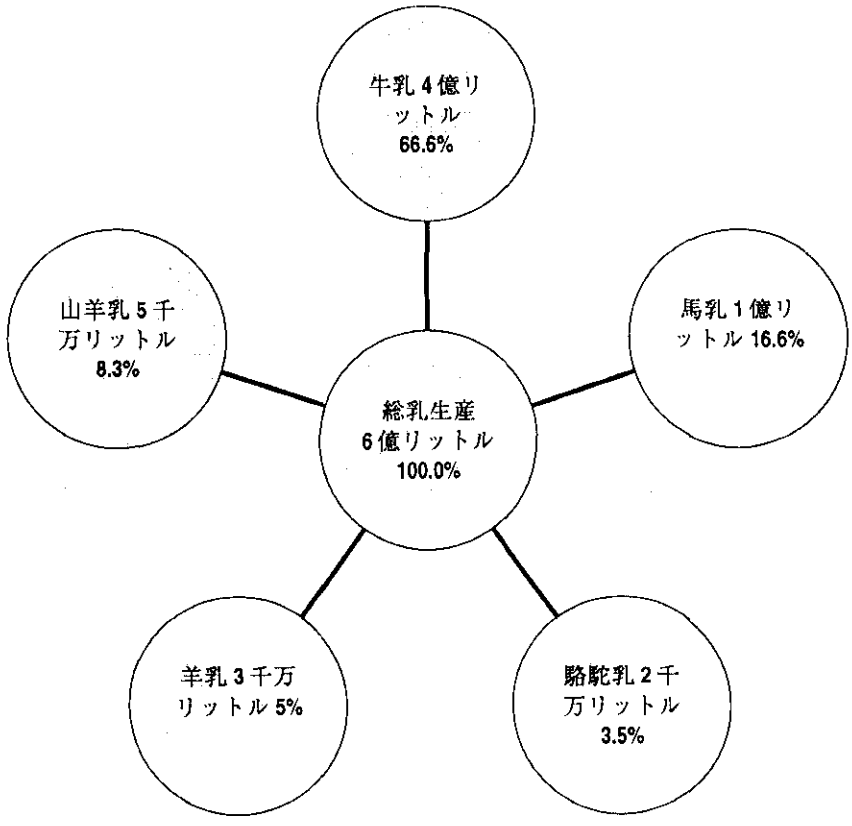




4. モンゴルの牛肉、羊肉、馬肉の主要生化学構成 (%)

主要構成要素	モンゴル			ニュージーランド		ロシア
	牛肉	羊肉	馬肉	牛肉	羊肉	馬肉
たんぱく質	18,82	20,35	20,11	17,14	21,31	19,50
脂肪	2,78	2,15	1,73	18,50	3,50	3,10
ミネラル	1,11	1,16	1,10	0,88	1,05	1,00
水分	75,76	75,47	76,06	62,84	74,1	75,90

図表 3. モンゴルの乳備蓄と種類



5. 羊肉に含まれる必須アミノ酸

(たんぱく質%)

種類	モンゴルの羊肉	キルギスタンのファイン・ウール用羊肉	ニュージーランドの羊肉
バリン	5.29	2.22	5.31
イソロイシン	4.98	1.62	4.76
ロイシン	8.21	7.65	7.7
リジン	9.22	7.55	8.74
メチオニン	3.03	2.68	2.61
トレオニン	4.82	3.71	4.80
トリプトファン	1.34		0.68
フェニルアラニン	4.75	2.20	4.49
合計	41.64	29.28	39.09

6. モンゴル羊肉を使用した場合、アミノ酸必要量に要する必須アミノ酸量

必須アミノ酸	1日当り必要摂取量	0.21 kgの肉に含まれている量（mg）	生理学的用件を満たす水準(%)
バリン	0.8	1.34	168.0
ロイシン	1.10	3.0	272.7
リジン	0.80	3.81	476.2
イソロイシン	0.7	1.14	162.8
フェニルアラニン	1.1	2.39	217.3
メチオニン	1.1	1.03	93.6
チレオニン	0.5	1.83	366.0
トリプトファン	0.25	0.76	304.0

7. 家畜筋肉の脂肪酸含有率(%)

構成物	モンゴル			ニュージーランド		ロシア
	羊	牛	馬	羊	牛	馬
飽和脂肪酸量	46.07	46.14	46.82	48.97	44.4	35.84
不飽和脂肪酸量	52.82	53.68	52.61	44.86	50.09	62.22
うちOXXX	7.13	8.08	22.71	2.38	5.90	14.27
C 18:2	5.26	5.73	16.48	1.47	4.37	11.86
C 18:3	1.42	0.68	2.50	0.91	1.53	2.16
C 18:4	0.45	1.17	1.66			

8. モンゴルの家畜乳の物理化学的構成

物理化学構成、単位			密度 Gr/cm³	総酸度 %	脂肪 %	たんぱく質 %	砂糖 %	灰 %	乾燥物 %
家畜の種類	牛	モンゴル種	1027.2-1032.1	18.0-19.0	3.10-5.40	3.15-3.75	4.54-4.80	0.72-0.84	12.51-18.2
		ヤク	1030.5-1034.9	21.0-22.0	4.20-8.00	3.70-6.10	4.84-5.50	0.76-0.93	13.60-20.0
		ヤク-牛の混種	1030.0-1034.9	19.0-22.0	7.10-6.80	3.60-5.15	4.13-5.15	0.70-1.21	13.40-19.6
	馬		1028.0-1030.0	8.10-8.70	2.20-2.40	2.20-3.10	7.00-7.80	0.30-0.38	11.6-13.68
	駱駝		1031.0-1032.0	16.5-17.2	5.17-5.65	3.91-4.39	3.97-4.76	0.67-0.87	13.7-15.67
	羊		1037.8-1039.8	27.1-29.7	5.52-5.82	5.26-6.48	3.78-5.00	0.91-1.20	15.47-18.5
	山羊		1031.0-1031.3	18.3-18.7	5.15-5.81	3.64-3.87	4.75-4.80	0.87-0.89	14.4-15.44

9. モンゴルにおける穀物生産

No	年	作付面積, 千ヘクタール	収穫量, 千トン	1ヘクタール当り収穫量, 100kg
1	1986-1990	830	633.0	12.7
2	1991-1995	342.8	404.1	8.6
3	1996-2000	219.05	188.4	6.8
4	1999	279.1	166.7	6.1
5	2000	194.7	138.2	7.2
6	2002	266.0	121.9	4.8

モンゴル政府は 2003 年に「品質保証改善のための方策」を発表するとともに、輸出入の品目リストおよび対象品目の税関管理に関する規則を作成した。モンゴル国会は「標準化および遵守評価法」を可決した。

1999 年以来実施されてきた研究の結果、食料品は輸入の 80%を占めることが明らかになった。こんにちでは食糧生産の質、衛生安全指標、試験方法に係る、国内規準 500、 ISO 規準 96、 CAC 規準 102 が 全国で蓄積されている。

近年モンゴルの人々は、生産技術における衛生面の危険を調査・管理し、品質管理システム USI9001、GMP の適切な生産システムを採用しようとする生産者のために、包括的なセミナー、訓練、HACCP 活動の導入等を図っている。

このような努力により、生産者および企業家は衛生安全性をより重視するようになっている。ウランバートルの食肉生産工場の 53 が下水処理を行っており、 そのうち 46 が衛生安全検査を受けた。検査の結果、20 社が危険、7 社が極めて危険とされ、そのうち 6.5%が衛生安全基準を遵守していなかった。11 社は基準に満たなかった。5 社は中央下水処理システムを利用していなかった。

こんにちでは、黴や菌など種々のバクテリアに汚染された食料品が輸入される危険性が高い。汚染されていると考えられるものは次のとおりである。
-放射性や基準以上の化学毒物が含まれているもの
-貯蔵や運送の途中で衛生安全の混乱が発生したもの
-医薬品、肥料、毒物などによって汚染されたもの

合計 470 社が小麦粉 9 万 1,100 トン、小麦 13 万 9,100 トンを輸入した。このうち小麦粉 8 万 9,900 トン (97%) 、小麦 9 万 3,700 トンが品質検査を受けなかった。231 のサンプルを検査した結果、194 のサンプルから硝酸カリが検出された。

11. 1人1日当り摂取カロリーと栄養素 (加重平均)

指標	2000	2001	2000 都市部	2001 都市部	2000 農村部	2001 農村部
カロリー (キロカロリー)	2462.3	2344.4	2099.6	2216.6	2841.8	2480.1
たんぱく質 (グラム)	105.4	93.6	85.0	81.9	125.7	106.0
脂肪 (グラム)	90.1	78.4	68.3	69.8	112.4	87.6
炭水化物 (グラム)	290.7	300.1	272.0	300.2	312.2	300.0

カロリー内容から、1人1日当りの食品消費量はわかるが、食品の栄養素までは分からない。最近の研究結果から、適切な食品消費量は1日2300-2500キロカロリーだと考えられる。モンゴル食の利点の一つは、摂取されるたんぱく質の60%が動物性であることである。反対にモンゴル人はジャガイモ、野菜、果物の消費量が少ないため不飽和脂肪酸、ビタミン、ミネラル、炭水化物が不足している。

機能的食品とは、たんぱく質、必須アミノ酸、珪藻炭水化物、不飽和脂肪酸、種々のビタミン、ミネラルなどあらゆる生物学的有効物質を含む食品で、代謝を高める働きがある。これらの食品の生産・流通の重要性は高まり、注目を集めている。

現在の課題を解決するための活動:

- 食品の調達と保証
- 品質と衛生安全
- 食品の栄養価向上

講演Ⅱ　櫻井　勇平

テキスト2

ЭРҮҮЛ АХУЙН ЭГЗЭГТЭЙ ЦЭГИЙН ШИНЖИЛГЭЭ (HACCP)

7 ЗАРЧИМ

БОЛОН

12 ХЭРЭГЖҮҮЛЭХ АРГА

ЭРҮҮЛ АХУЙН ЭГЗЭГТЭЙ ЦЭГИЙН ХЯНАЛТЫН СИСТЕМИЙН ЗАРЧМУУД

ЭАЭЦШ-ын систем нь дараахь 7 зарчмаас бүрддэг

ЗАРЧИМ 1
Нөлөөллийн шинжилгээг явуулах

ЗАРЧИМ 2
Эгзэгтэй цэгүүдийг тодорхойлох

ЗАРЧИМ 3
Эгзэгтэй цэг бүрийн хязгаарыг тогтоох

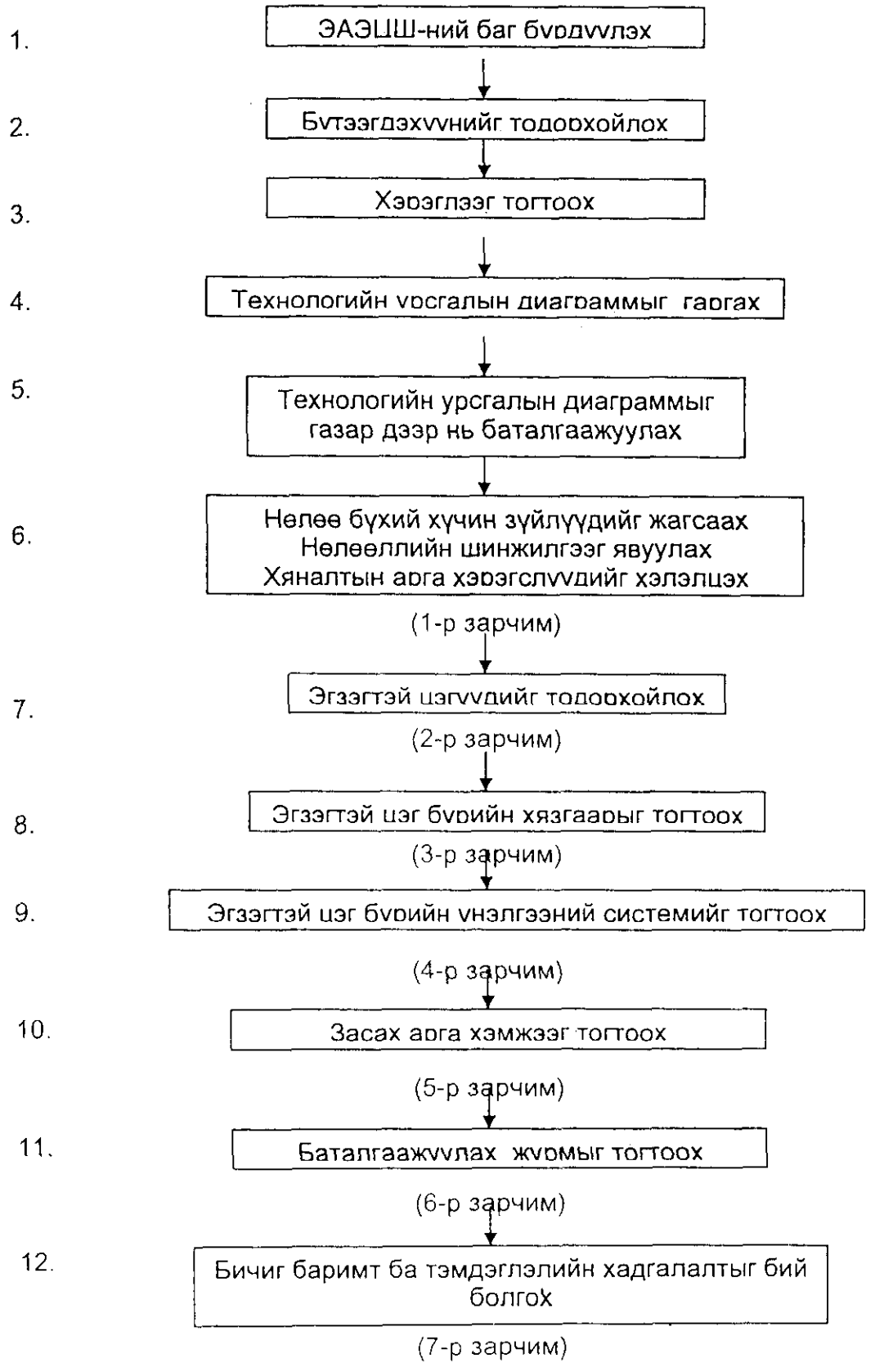
ЗАРЧИМ 4
Эгзэгтэй цэг бүрийн үнэлгээний системийг тогтоох

ЗАРЧИМ 5
Тухайн эгзэгтэй цэг нь үнэлгээний системд хамрагдаагүй тохиолдолд засах арга хэмжээг тогтоох

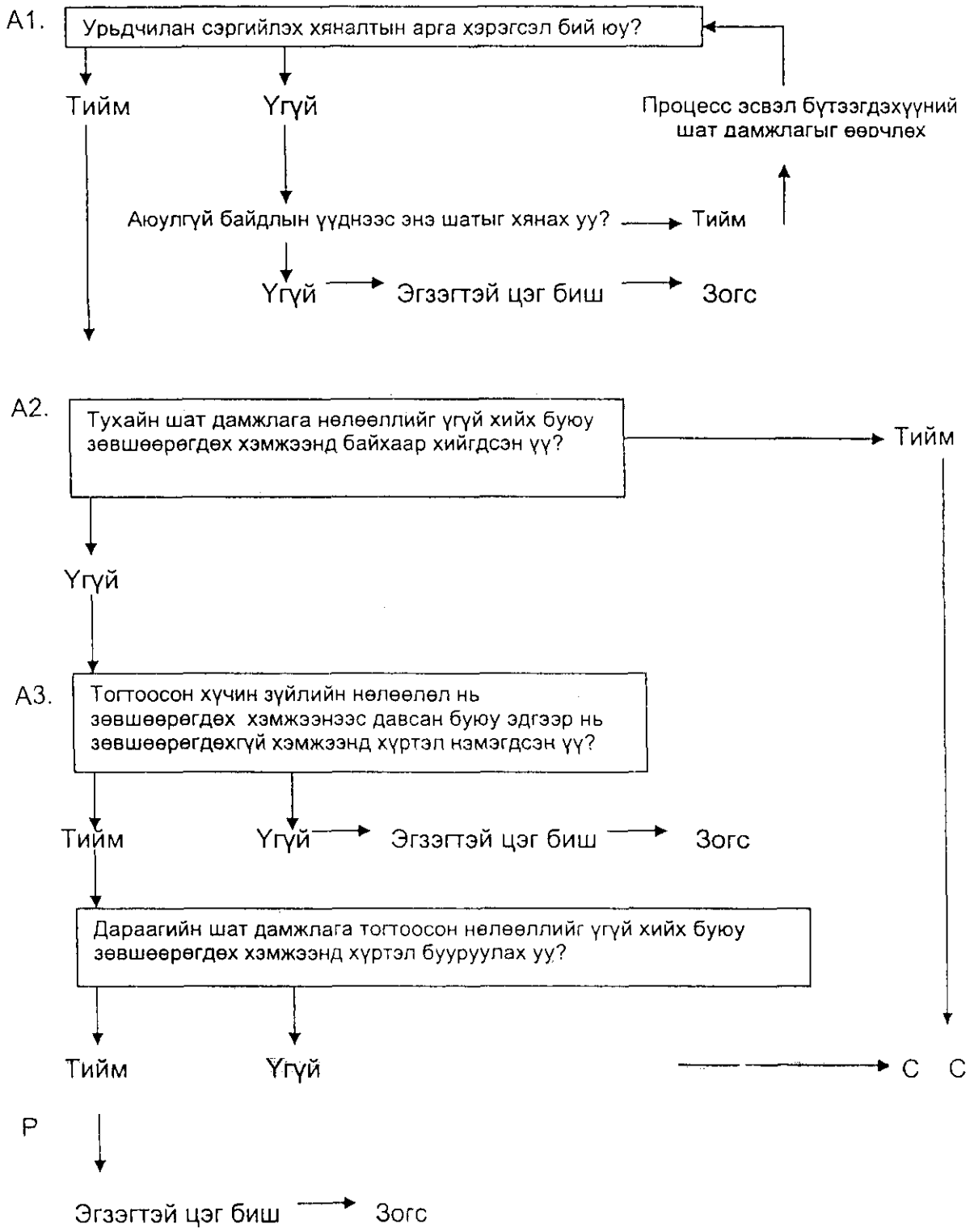
ЗАРЧИМ 6
ЭАЭЦШ-ын систем нь үр дүнтэй хэрэгжиж байгааг *Баталгаажуулах* журмыг тогтоох

ЗАРЧИМ 7
Энэхүү зарчмуудтай холбоотой бичиг баримт болон тэмдэглэлийн хадгалалтыг бий болгох

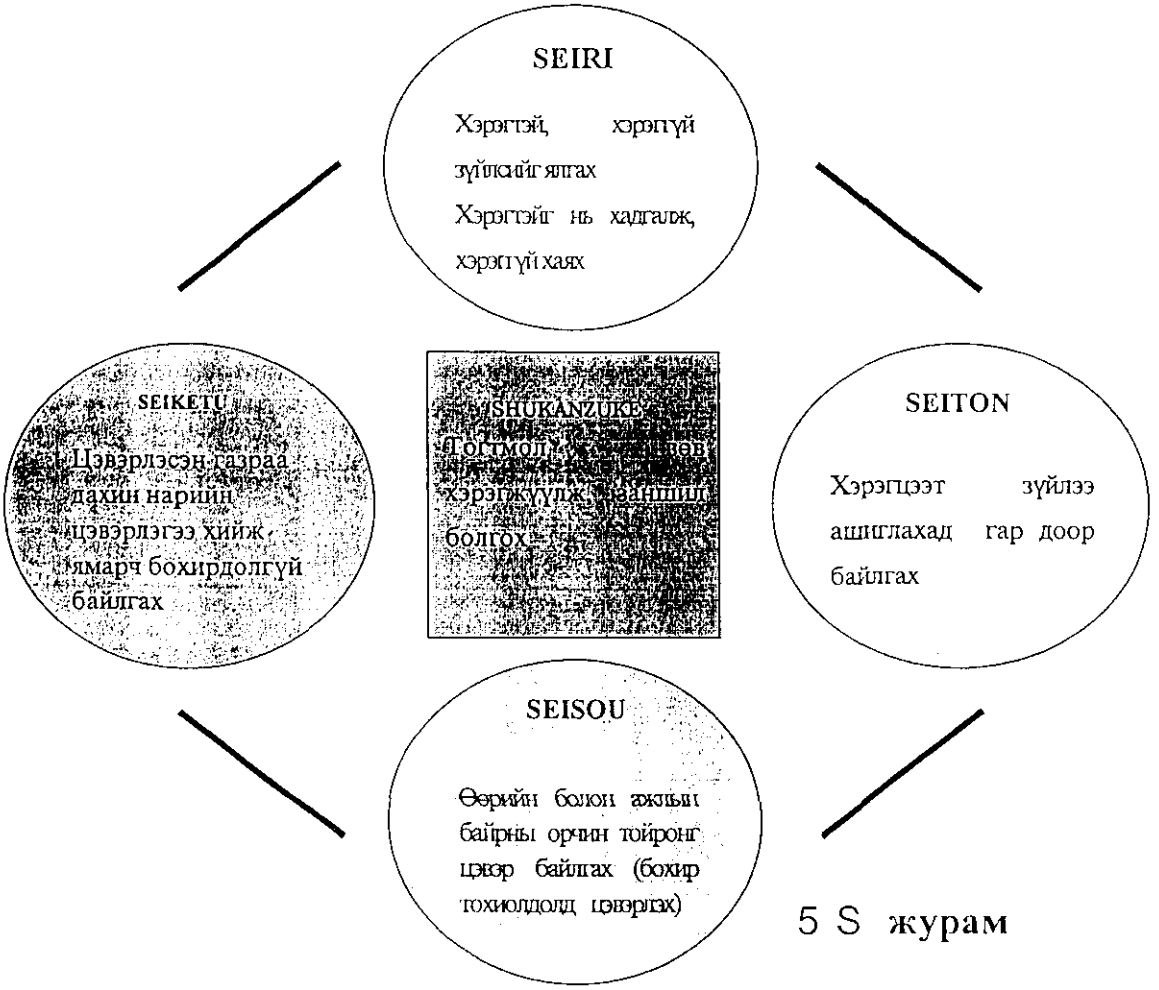
HACCP - Эрүүл ахуйн эгзэгтэй цэгийн шинжилгээ хийх логик дараалал



Эгзэгтэй цэгүүдийг тогтооход шийдвэр гаргах жишээ



5 S болон PDCA циклийг хэрэгжүүлвэл хэрэглэгчдийн гомдол багасна



5 S журам

PLAN – төлөвлөх
DO - хийх
CHECK - хянах
ACTION - сайжруулах

Урагшлах

P D C A хяналтын цикл

Эгзэгтэй цэгийн шинжилгээ хийх ажлын хуудасны жишээ

1. Бүтээгдэхүүнээ дүрсэл

2. Технологийн урсгалын диаграмм

3.

Хуудас							
Шат дамж-лага	Хүчин зүйлүүд	Хяналтын арга хэрэгсэл	Эгзэгтэй цэгүүд	Хязгаар	Хяналтын процес-сууд	Засах арга хэмжээ	Тэмдэг лэл

4. Баталгаажуулах

Тайлбар

Хянах: HACCP төлөвлөгөөнд тогтоосон шалгууруудыг батлах ба хангах бүх шаардлагатай арга хэмжээг авах

Хяналт: Зөв журам мөрдүүлэх ба шалгууруудыг хангуулах нөхцөл байдал

Хяналтын хэрэгсэл: Хүнсний аюулгүй байдалд нөлөөлөх нөлөөллөөс урьдчилан сэргийлэх буюу түүнийг арилгах, эсвэл түүнийг зөвшөөрөгдөх хэмжээ хүртэл бууруулахад ашиглаж болох аливаа үйл ажиллагаа

Засах арга хэмжээ: Эгзэгтэй цэгийн шинжилгээгээр үнэлгээний үр дүн нь хяналт буруу байгааг үзүүлэх тохиолдолд авч явуулах аливаа арга хэмжээ

Эгзэгтэй цэг: Хүнсний аюулгүй байдлын эрсдэлээс урьдчилан сэргийлэх буюу түүнийг арилгах, эсвэл түүнийг зөвшөөрөгдөх хэмжээ хүртэл бууруулах ашиглаж болох аливаа үйл ажиллагаа

Хязгаар: Үл зөвшөөрөгдөхөөс зөвшөөрөгдөх хүртэл ангилсан үзүүлэлтүүд

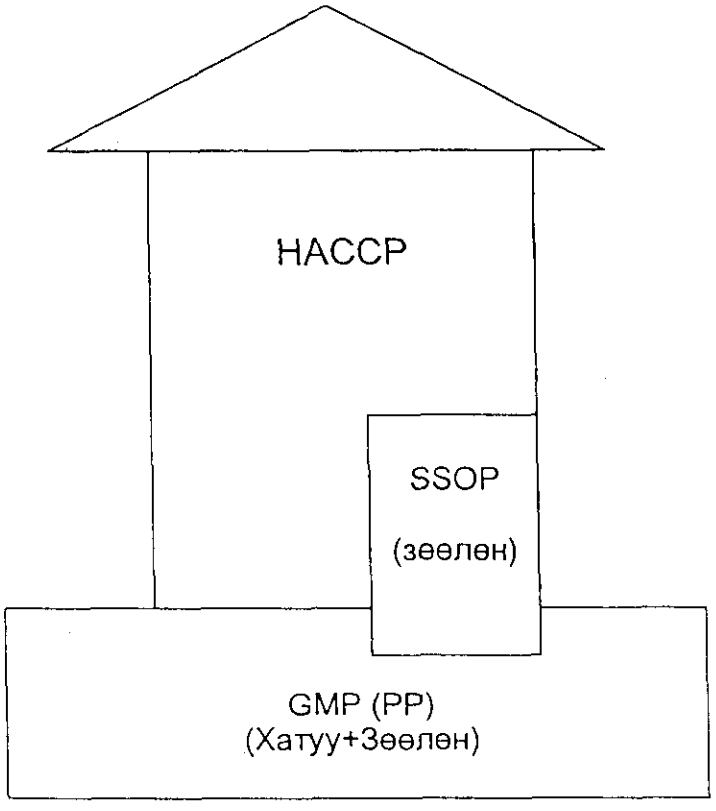
Техонологийн урсгалын диаграмм: Тодорхой хүнсний зүйлийг боловсруулах, үйлдвэрлэх шат дамжлага ба ажиллагааны дараалллыг системтэй харуулсан дүрслэл

HACCP: Хүнсний аюулгүй байдалд чухал эрсдэлүүдийг тогтоох, үнэлэх ба хянах систем

HACCP төлөвлөгөө: HACCP зарчмын дагуу бэлтгэсэн, хүнсний аюулгүй байдалд чухал хүчин зүйлүүдийн нөлөөллүүдийн хяналтыг хангах баримт бичиг

HAZARD: Эрүүл мэндэд сөрөг үр дагавар учруулах хүнсний бүтээгдэхүүний биологи, химийн буюу физик хүчин зүйл эсвэлтөлөв байдал

HACCP · PP · GMP · SSOP



HACCP: Hazard Analysis Critical Control Point
Эрүүл ахуйн эгзэгтэй цэгийн шинжилгээ

PP: Prerequisite Program
Урьдчилсан шаардлагын хөтөлбөр

GMP: Good Manufacturing Procedure
Бараа үйлдвэрлэх журам

SSOP: Standard Sanitation Operation Procedure
Ариутгал хийх журмын стандарт

テキスト3

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

FOOD HYGIENE – BASIC TEXTS

CONTENTS

PREFACE

THE CODEX ALIMENTARIUS COMMISSION AND THE FAO/WHO FOOD STANDARDS PROGRAMME

The Codex Alimentarius Commission implements the Joint FAO/WHO Food Standards Programme, the purpose of which is to protect the health of consumers and to ensure fair practices in the food trade. The *Codex Alimentarius* (Latin, meaning Food Law or Code) is a collection of internationally adopted food standards presented *in a uniform manner*. It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures to assist in achieving the purposes of the Codex Alimentarius. The Commission has expressed the view that codes of practice might provide useful checklists of requirements for national food control or enforcement authorities. The publication of the *Codex Alimentarius* is intended to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in their harmonization and, in doing so, to facilitate international trade.

BASIC TEXTS ON FOOD HYGIENE

In June 1997 the Codex Alimentarius Commission adopted three newly revised basic texts on food hygiene. These texts are published officially *in Volume* 1B of the *Codex Alimentarius* and have been republished in this compact format to allow their wide use and understanding by governments, regulatory authorities, food industries and all food handlers, and consumers.

Further information on these texts, or any other aspect of the Codex Alimentarius Commission, may be obtained from:

The Secretary,
Codex Alimentarius Commission,
Joint FAO/WHO Food Standards Programme,
FAO, Viale delle Terme di Caracalla,
00100, Rome Italy

fax: +39(6)57.05.45.93
email: codex@fao.org

HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION

Annex to CAC/RCP 1-1969, Rev. 3 (1997)

PREAMBLE

The first section of this document sets out the principles of the Hazard Analysis and Critical Control Point (HACCP) system adopted by the Codex Alimentarius Commission. The second section provides general guidance for the application of the system while recognizing that the details of application may vary depending on the circumstances of the food operation.[1]

The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering, according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as the

[1] The Principles of the HACCP System set the basis for the requirements for the application of HACCP, while the Guidelines for the Application provide general guidance for practical application.

ISO 9000 series, and is the system of choice in the management of food safety within such systems.

While the application of HACCP to food safety was considered here, the concept can be applied to other aspects of food quality.

DEFINITIONS

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical Control Point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety in the segment of the food chain under consideration.

Hazard: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that the elements of the HACCP plan are effective.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

PRINCIPLES OF THE HACCP SYSTEM

The HACCP system consists of the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish critical limit(s).

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

PRINCIPLE 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

Prior to application of HACCP to any sector of the food chain, that sector should be operating according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety legislation. Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to the impact of raw materials, ingredients, food manufacturing practices, role of manufacturing processes to control hazards, likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found.

HACCP should be applied to each specific operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature.

The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

It is important when applying HACCP to be flexible where appropriate, given the context of the application taking into account the nature and the size of the operation.

APPLICATION

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

1. Assemble HACCP team

The food operation should ensure that the appropriate product specific knowledge and expertise is available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

2. Describe product

A full description of the product should be drawn up, including relevant safety information such as: composition, physical/chemical structure (including A_w, pH, etc.), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution.

3. Identify intended use

The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

4. Construct flow diagram

The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

5. *On-site confirmation of flow diagram*

The HACCP team should confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate.

6. *List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards*

(SEE PRINCIPLE 1)

The HACCP team should list all of the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption.

The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of microorganisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents and;
- conditions leading to the above.

The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard.

More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

7. *Determine Critical Control Points*

(SEE PRINCIPLE 2)[2]

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g. Diagram 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. This example of a decision tree may not be applicable to all situations. Other approaches may be used. Training in the application of the decision tree is recommended.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

8. *Establish critical limits for each CCP*

(SEE PRINCIPLE 3)

Critical limits must be specified and validated if possible for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include measurements of temperature, time, moisture level, pH, A_w, available chlorine, and sensory parameters such as visual [illegible] and textu[illegible]

[2] Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

9. *Establish a monitoring system for each CCP*

(SEE PRINCIPLE 4)

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company.

10. *Establish corrective actions*

(SEE PRINCIPLE 5)

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

11. *Establish verification procedures*

(SEE PRINCIPLE 6)

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include:

- Review of the HACCP system and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

12. *Establish Documentation and Record Keeping*

(SEE PRINCIPLE 7)

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

Documentation examples are:

- Hazard analysis;
- CCP determination;
- Critical limit determination.

Record examples are:

- CCP monitoring activities;
- Deviations and associated corrective actions;
- Modifications to the HACCP system.

An example of a HACCP worksheet is attached as Diagram 3.

TRAINING

Training of personnel in industry, government and academia in HACCP principles and applications, and increasing awareness of consumers are essential elements for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to be stationed at each Critical Control Point.

Cooperation between primary producer, industry, trade groups, consumer organizations, and responsible authorities is of vital importance. Opportunities should be provided for the joint training of industry and control authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

DIAGRAM 1
LOGIC SEQUENCE FOR THE APPLICATION OF HACCP

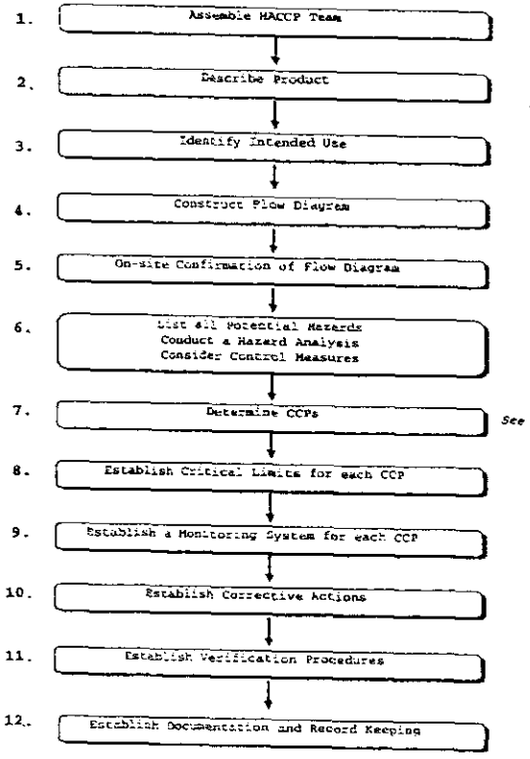


DIAGRAM 2
EXAMPLE OF DECISION TREE TO IDENTIFY CCPS
(answer questions in sequence)

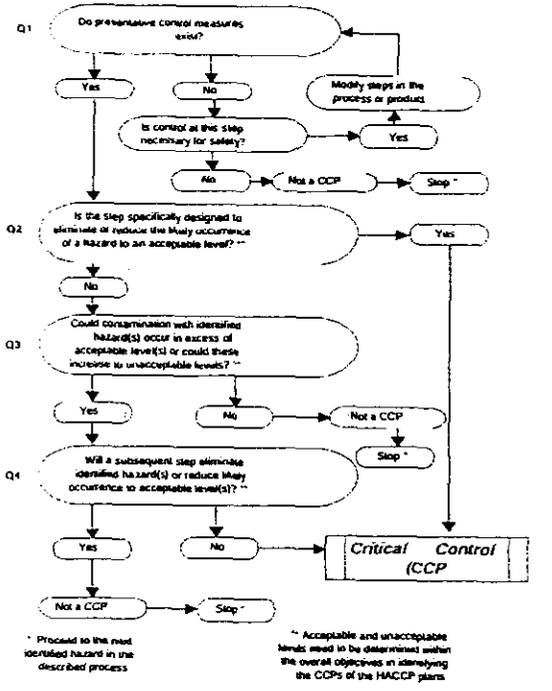


DIAGRAM 3

EXAMPLE OF A HACCP WORKSHEET

1. Describe Product

2. Diagram Process Flow

3. List

Step	Hazard(s)	Control Measure(s)	CCPs	Critical Limits	Monitoring Procedures	Corrective Actions	Records

4. Verification

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テキスト４

ИСО

Японы Хөлдөөсөн Бүтээгдэхүүнийг Магадлан Шалгах Байгууллага

Ерөнхий менежер Абе Норио

1. ИСО гэдэг нь

Олон Улсын Стандартын Байгууллага (International Organization for Standardization)

Бүтээгдэхүүн болон үйлчилгээний олон улсын стандартыг боловсруулах, батлах, гишүүн орнуудад мөрдүүлэх үйл ажиллагаа явуулдаг.

2. ИСО-г стандартын жишээ

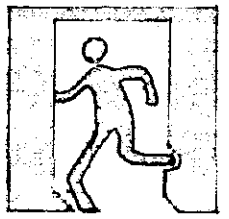
Хальс

Боолт

Нөөц хаалга

IS0100

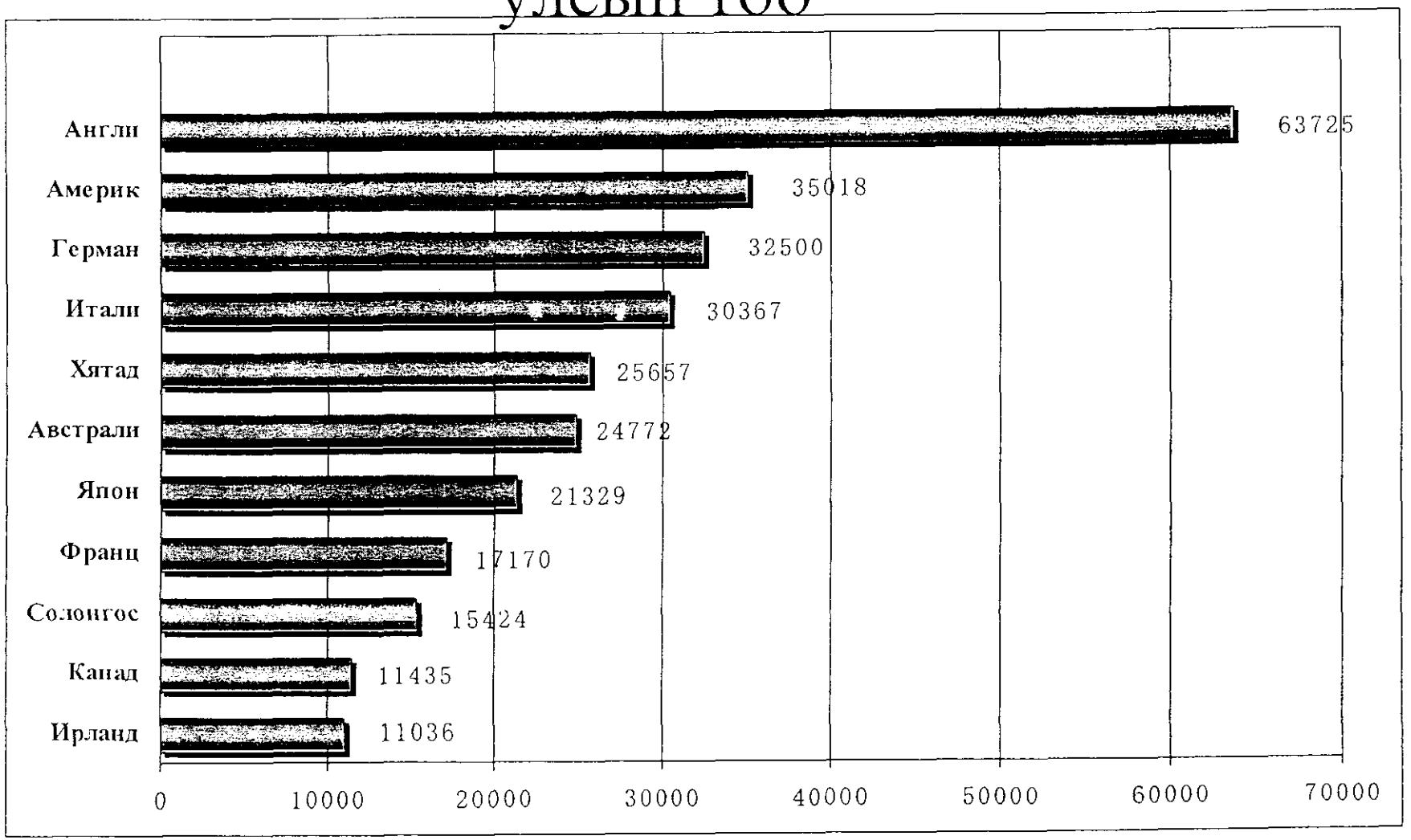
IS0400



Менежмент болон систем

■ IS0900 1
(1987гаргасан)

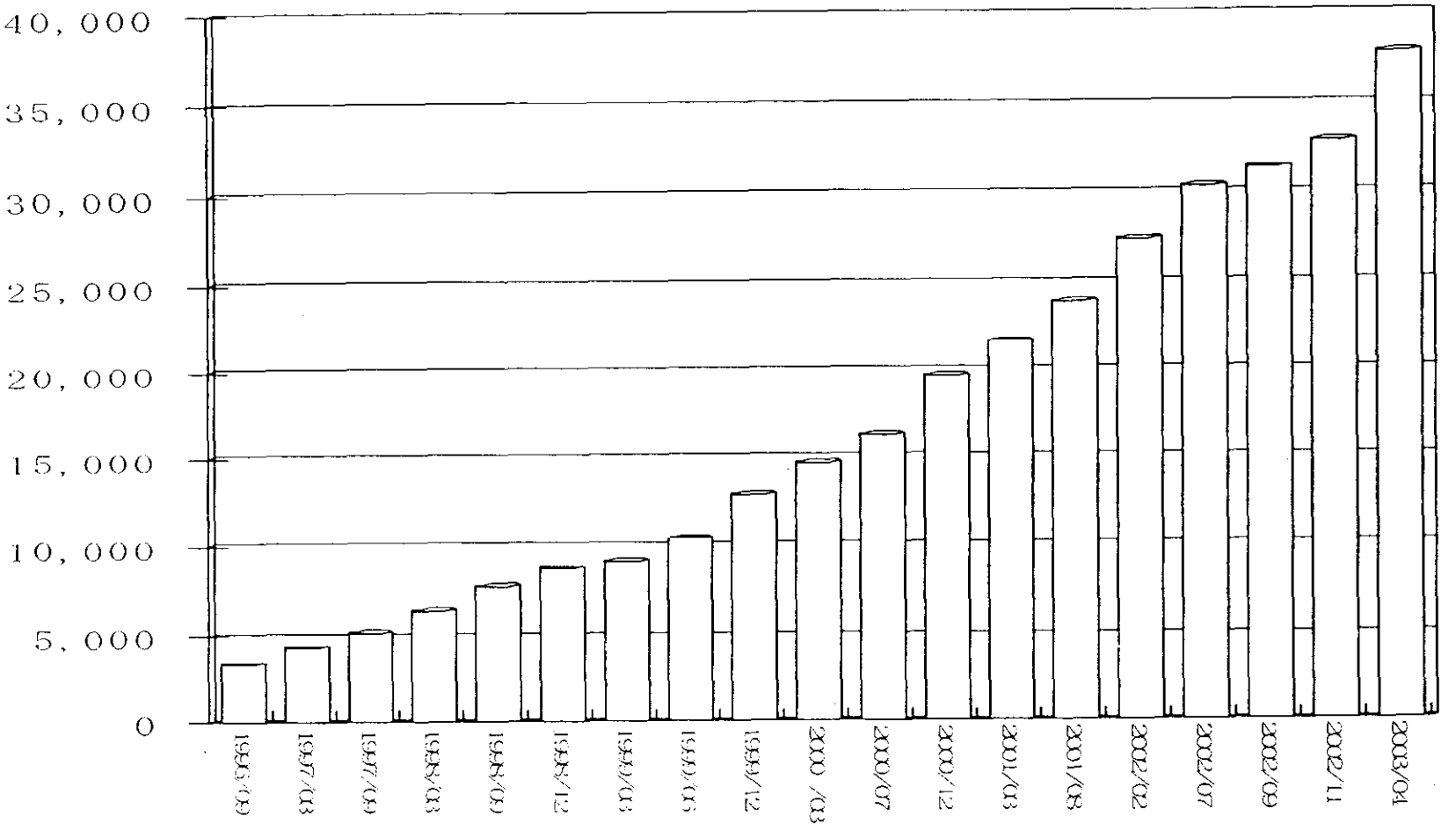
3. ИСО 9 0 0 1 : Гэрчилгээг авсан улсын тоо



4. ISO9001 : Япон улс ИСО9001 гэрчилгээг авсан тоо баримт

2003 оны 4-р сард 37,786

Жилийн туршид (2002／4～2003／3) өсөлт 7,700



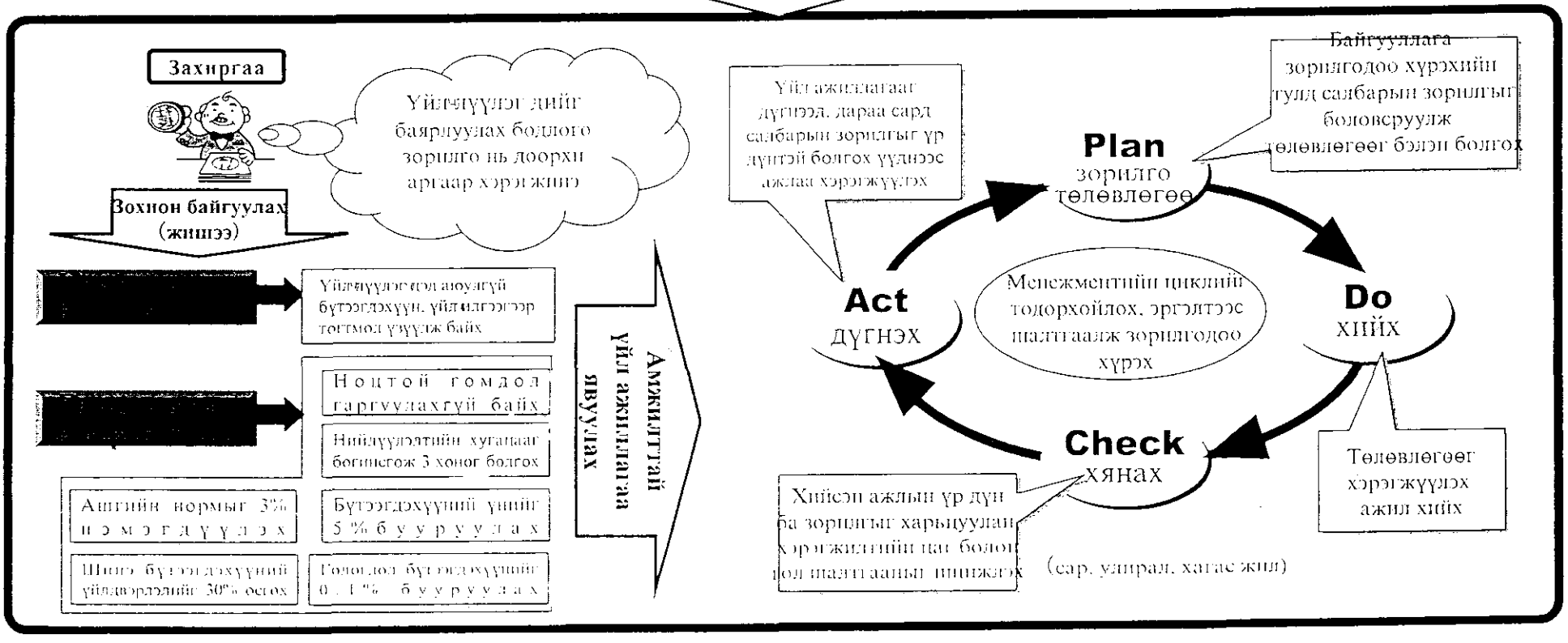
5 Чанарын менежментийн систем

4．1　Ерөнхий шаардлага

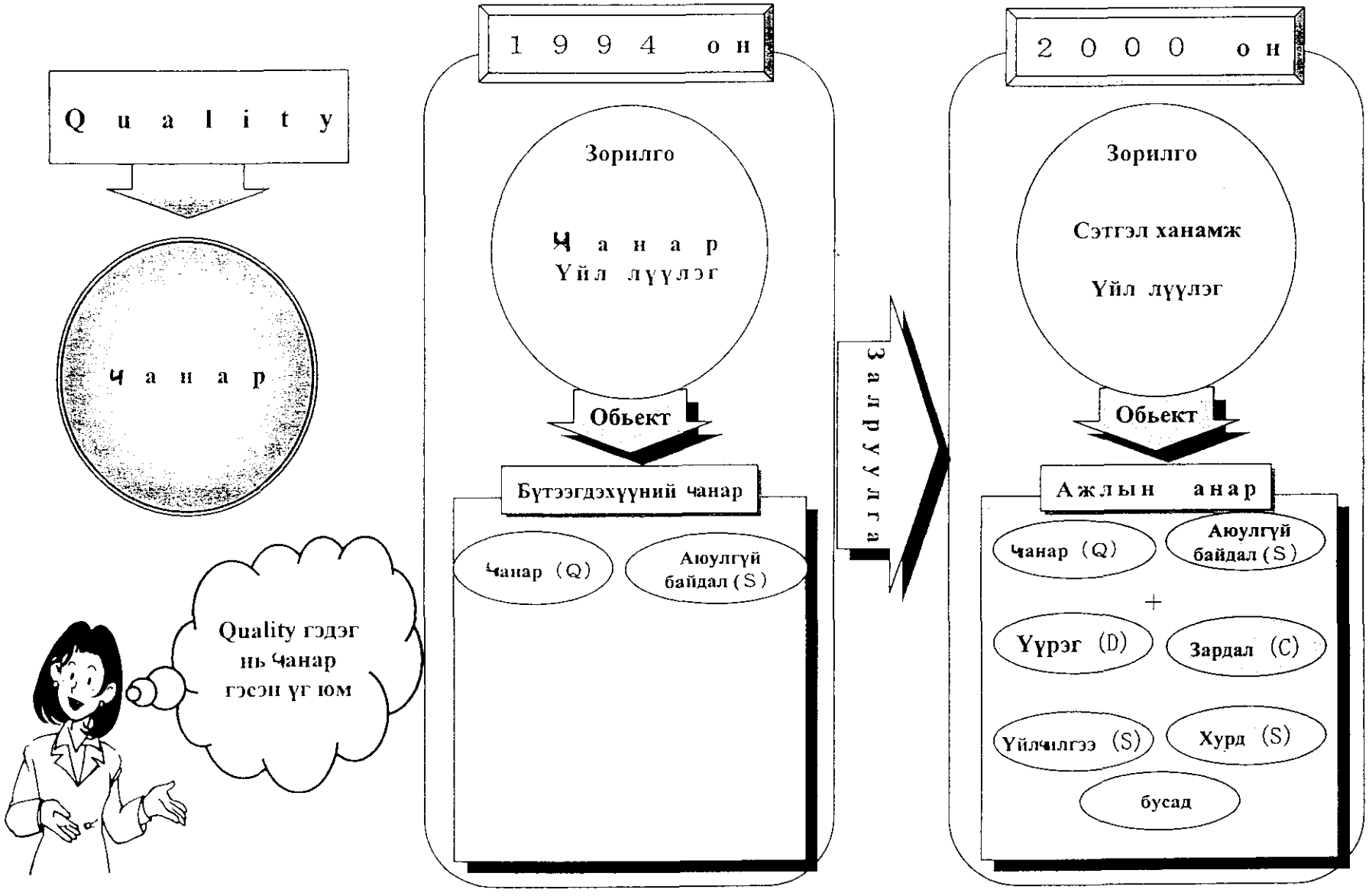
Чанарын менежментийн системийн зохион байгуулалт гэдэг нь тухайн системийн шаардлагад тулгуурласан үйл ажиллагааг төлөвлөх, хийх, хянах, дүгнэхээс гадна тухайн чанарын менежментийн системийг үр дүнтэй үргэлжлүүлэн сайжруулахад оршдог.

Чанарын менежментийн систем → **Чанарын бодлого болон зорилтыг тодорхойлох, хэрэгжүүлэхэд ИСО 9000 системийн тодорхойлолтыг хялбар болон ойлгомтойгоор цэгэрхийлэх хэрэгтэй**

Тодорхойд нь



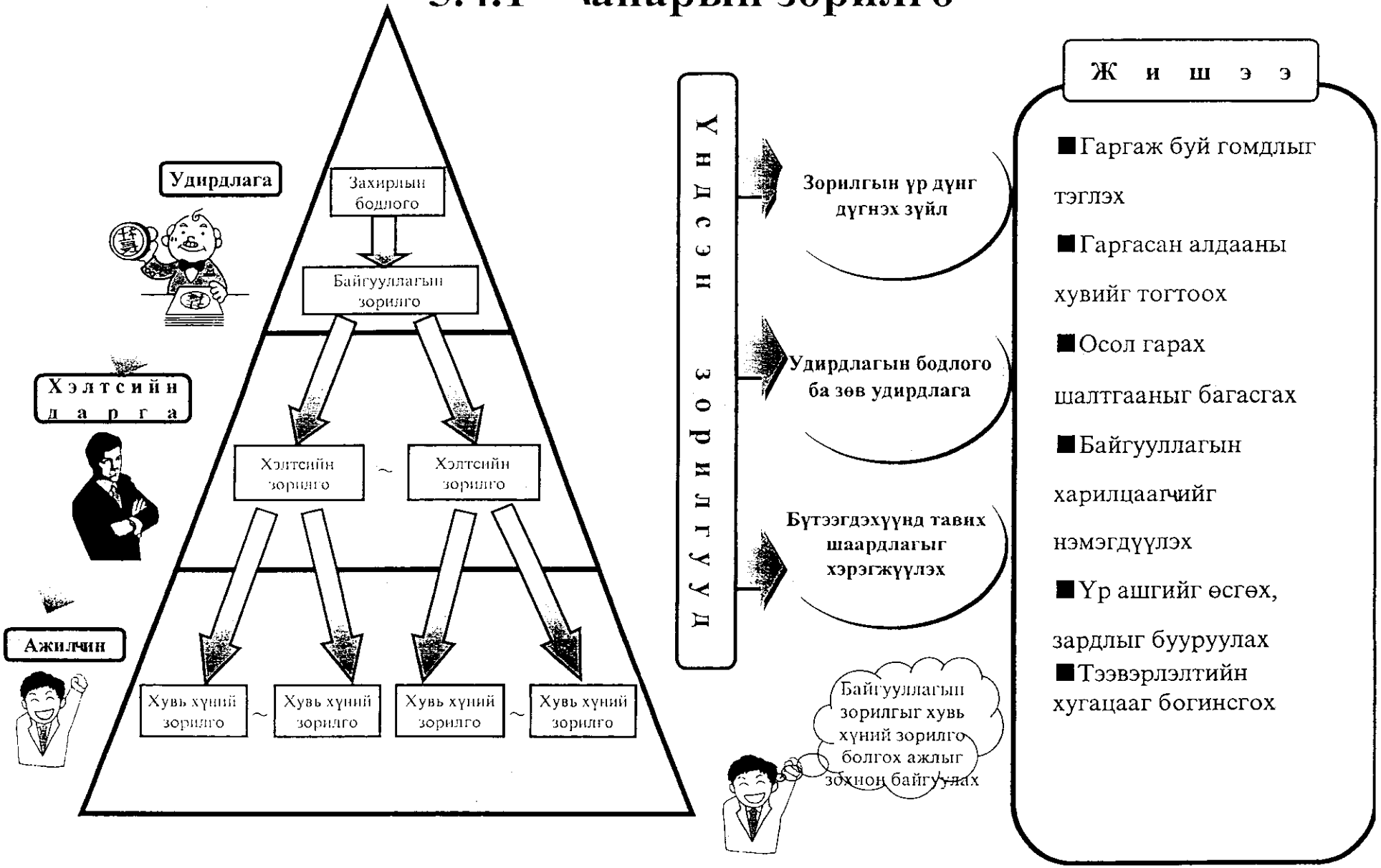
6. ИСО 9001 : Чанарын баталгааг үйлчлүүлэгчийн шаардлагад нийцүүлэх



7. ИСО 9001Стандартын тов÷ утга

5	*Удирдлагын хариуцлага*	5.1	Удирдлагын үүрэг	1
		5.2	Худалдан авагчийг эрхэмлэх	1
		5.3	Бүтээгдэхүүний чанарын бодлого	1
		5.4	Төлөвлөгөө	2
		5.5	Хариуцагч, эрх мэдэл, харилцаа	3
		5.6	Менежментийн хяналт	3
6	*Нөөцийн удирдлага*	6.1	Нөөцийн нийлүүлэлт	1
		6.2	Хүний нөөц	2
		6.3	Дэд бүтэц	1
		6.4	Байгууллагын орчин	1
7	*Бүтээгдэхүүн үйлчилгээг бий болгох*	7.1	Бүтээгдэхүүний биелэлтийн төл-гөө	1
		7.2	Худалдан авагчтай харилцах	3
		7.3	Төлөвлөгөө боловсруулах	7
		7.4	Худалдан авах	3
		7.5	Үйлдвэрлэл ба үйлчилгээг нэвтрүүлэ	5
		7.6	Хянах, хэмжих машины хяналт	1
8	*Хэмжих, шинжлэх, сайжруулах*	8.1	Ерөнхий	1
		8.2	Хянах ба хэмжиж үзэх	4
		8.3	Гологдол барааны хяналт	1
		8.4	Мэдээллийн шинжилгээ	1
		8.5	Сайжруулах	3
	ДҮН	23		51

8. 5 Удирдлагын үүрэг хариуцлага 5.4 Төлөвлөгөө 5.4.1 чанарын зорилго



テキスト5

JAPANESE INDUSTRIAL STANDARD

JIS Q 9001 (ISO 9001)

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

Reference number
JIS Q 9001:2000

Contents

Annexes

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management* and *quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.

The title of ISO 9001 has been revised in this edition and no longer includes the term "Quality assurance". This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.

Annexes A and B of this International Standard are for information only.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

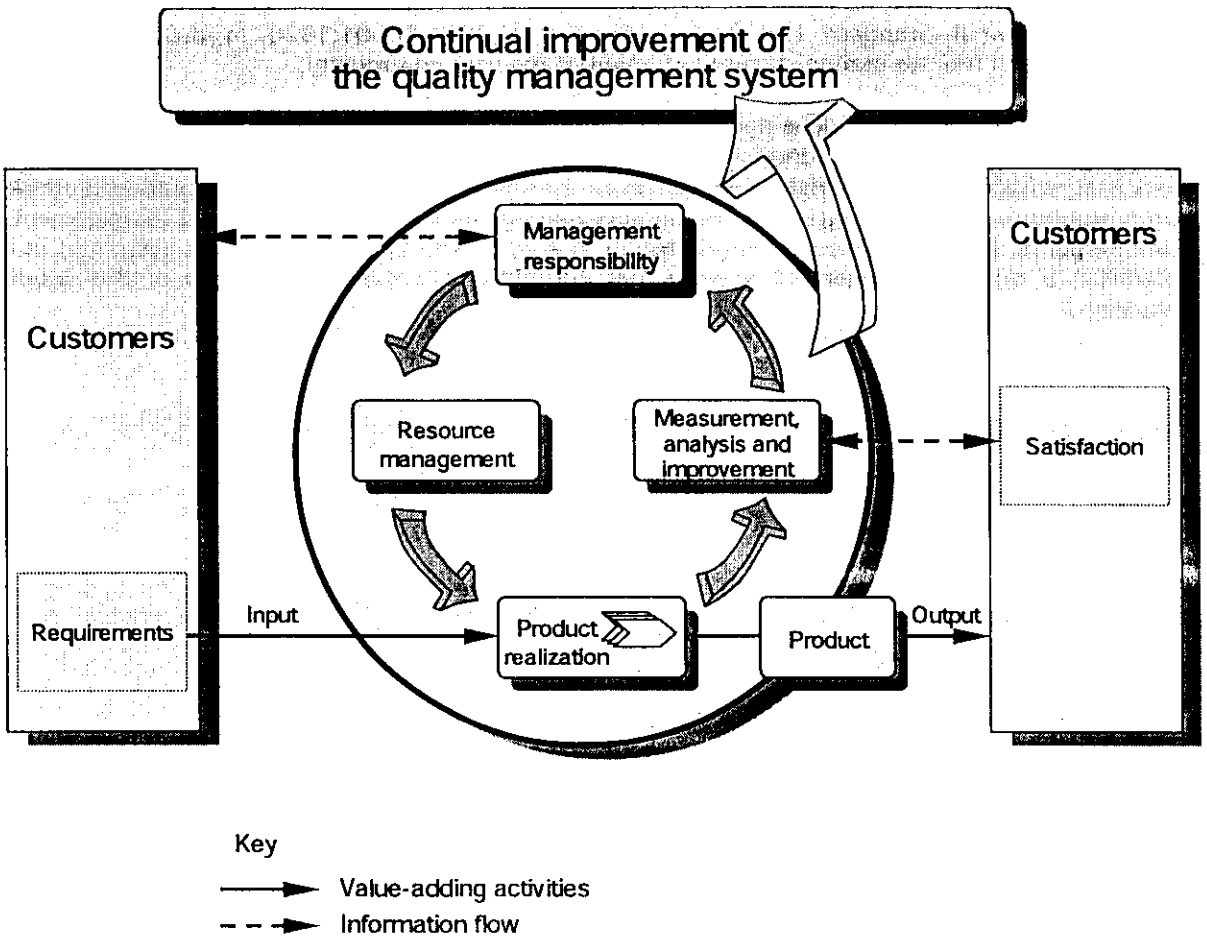


Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Quality management systems - Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable regulatory requirements.

NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements.

2 Normative reference

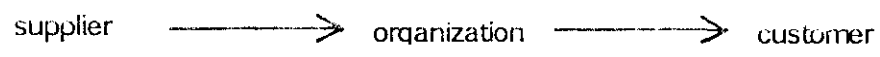
The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000: 2000, *Quality management systems - Fundamentals and vocabulary.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply.

The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:



The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

5 Management responsibility

5.1 anagement commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a]], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.

6.2.2 Competence, awareness and training

The organization shall

a) determine the necessary competence for personnel performing work affecting product quality,

b) provide training or take other actions to satisfy these needs,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport or communication).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes, documents, and provide resources specific to the product;

c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements related to the product, and

d) any additional requirements determined by the organization.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and for service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including where appropriate

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring devices,

e) the implementation of monitoring and measurement, and

f) the implementation of release, delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4.2.4), and

e) revalidation.

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;

b) be adjusted or re-adjusted as necessary;

c) be identified to enable the calibration status to be determined;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE See ISO 10012-1 and ISO 10012-2 for guidance.

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity of the product,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1).

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),

b) conformity to product requirements (see 7.2.1),

c) characteristics and trends of processes and products including opportunities for preventive action, and

d) suppliers.

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities ,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken (see 4.2.4), and

f) reviewing corrective action taken.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of results of action taken (see 4.2.4), and

e) reviewing preventive action taken.

Annex A
(informative)

Correspondence between ISO 9001:2000 and ISO 14001:1996

Table A.1 - Correspondence between ISO 9001:2000 and ISO 14001:1996

ISO 9001:2000		ISO 14001:1996	
Introduction			**Introduction**
General	0.1		
Process approach	0.2		
Relationship with ISO 9004	0.3		
Compatibility with other management systems	0..4		
Scope	1	1	**Scope**
General	1.1		
Application	1.2		
Normative reference	2	2	**Normative references**
Terms and definitions	3	3	**Definitions**
Quality management system	4	4	**Environmental management system requirements**
General requirements	4.1	4.1	General requirements
Documentation requirements	4.2		
General	4.2.1	4.4.4	Environmental management system
Quality manual	4.2.2	4.4.4	documentation
Control of documents	4.2.3	4.4.5	Environmental management system
Control of records	4.2.4	4.5.3	*documentation*
			Document control
			Records
Management responsibility	5	4.4.1	**Structure and responsibility**
Management commitment	5.1	4.2	Environmental policy
		4.4.1	Structure and responsibility
Customer focus	5.2	4.3.1	Environmental aspects
		4.3.2	Legal and other requirements
Quality policy	5.3	4.2	Environmental policy
Planning	5.4	4.3	Planning
Quality objectives	5.4.1	4.3.3	Objectives and targets
Quality management system planning	5.4.2	4.3.4	Environmental management programme(s)
Responsibility, authority and communication	5.5	4.1	General requirements
Responsibility and authority	5.5.1	4.4.1	Structure and responsibility
Management representative			
Internal communication	5.5.3	4.4.3	Communication
Management review	5.6	4.6	*Management review*
General	5.6.1		
Review input	5.6.2		
Review output	5.6.3		
Resource management	6	4.4.1	Structure and responsibility
Provision of resources	6.1		
Human resources	6.2		
General	6.2.1		
Competence, awareness and training	6.2.2	4.4.2	Training, awareness and competence

ISO 9001:2000		ISO 14001:1996	
Infrastructure	6.3	4.4.1	Structure and responsibility
Work environment	6.4		

Table A.1 - Correspondence between ISO 9001:2000 and ISO 14001:1996 *(continued)*

ISO 9001:2000		ISO 14001:1996	
Product realization	**7**	**4.4** **4.4.6**	**Implementation and operation** **Operational control**
Planning of product realization Customer-related processes	7.1 7.2	4.4.6	Operational control
Determination of requirements related to the product	7.2.1	4.3.1 4.3.2 4.4.6	Environmental aspects Legal and other requirements Operational control
Review of requirements related to the product	7.2.2	4.4.6 4.3.1	Operational control Environmental aspects
Customer communication	7.2.3	4.4.3	Communications
Design and development Design and development planning Design and development inputs Design and development outputs Design and development review Design and development verification Design and development validation Control of design and development changes	7.3 7.3.1 7.3.2 7.3.3 7.3.4 7.3.5 7.3.6 7.3.7	4.4.6	Operational control
Purchasing Purchasing process Purchasing information Verification of purchased product	7.4 7.4.1 7.4.2 7.4.3	4.4.6	Operational control
Production and service provision Control of production and service provision Validation of processes for production and service provision Identification and traceability Customer property Preservation of product	7.5 7.5.1 7.5.2 7.5.3 7.5.4 7.5.5	4.4.6	Operational control
Control of monitoring and measuring devices	7.6	4.5.1	Monitoring and measurement
Measurement, analysis and improvement	**8**	4.5	Checking and corrective action
General Monitoring and measurement Customer satisfaction	8.1 8.2 8.2.1	4.5.1	Monitoring and measurement
Internal audit	8.2.2	4.5.4	Environmental management system audit
Monitoring and measurement of processes Monitoring and measurement of product	8.2.3 8.2.4	4.5.1	Monitoring and measurement
Control of nonconforming product	8.3	4.5.2 4.4.7	Nonconformance and corrective and preventive action Emergency preparedness and response
Analysis of data	8.4	4.5.1	Monitoring and measurement
Improvement	8.5	4.2	Environmental policy
Continual improvement	8.5.1	4.3.4	Environmental management programme(s)
Corrective action	8.5.2	4.5.2	Nonconformance and corrective and preventive action

ISO 9001:2000		ISO 14001:1996	
Preventive action	8.5.3		

Table A.2 - Correspondence between ISO 14001:1996 and ISO 9001:2000

ISO 14001:1996		ISO 9001:2000	
Introduction	—	**0**	**Introduction**
		0.1	General
		0.2	Process approach
		0.3	Relationship with ISO 9004
		0.4	Compatibility with other management systems
Scope	**1**	**1**	**Scope**
		1.1	General
		1.2	Application
Normative references	**2**	**2**	**Normative reference**
Definitions	**3**	**3**	**Terms and definitions**
Environmental management system requirements	**4**	**4**	**Quality management system**
General requirements	4.1	4.1	General requirements
		5.5	Responsibility, authority and communication
		5.5.1	Responsibility and authority
Environmental policy	4.2	5.1	Management commitment
		5.3	Quality policy
		8.5	Improvement
Planning	4.3	5.4	Planning
Environmental aspects	4.3.1	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
Legal and other requirements	4.3.2	5.2	Customer focus
		7.2.1	Determination of requirements related to the product
Objectives and targets	4.3.3	5.4.1	Quality objectives
Environmental management programme(s)	4.3.4	5.4.2	Quality management system planning
		8.5.1	Continual improvement
Implementation and operation	4.4	**7**	**Product realization**
		7.1	Planning of product realization
Structure and responsibility	4.4.1	**5**	**Management responsibility**
		5.1	Management commitment
		5.5.1	Responsibility and authority
		5.5.2	Management representative
		6	**Resource management**
		6.1	Provision of resources
		6.2	Human resources
		6.2.1	General
		6.3	Infrastructure
		6.4	Work environment
Training, awareness and competence	4.4.2	6.2.2	Competence, awareness and training
Communication	4.4.3	5.5.3	Internal communication
		7.2.3	Customer communication
Environmental management system documentation	4.4.4	4.2	Documentation requirements
		4.2.1	General
		4.2.2	Quality manual

Table A.2 - Correspondence between ISO 14001:1996 and ISO 9001:2000 *(continued)*

ISO 14001:1996		ISO 9001:2000	
Document control	4.4.5	4.2.3	Control of documents
Operational control	4.4.6	7	**Product realization**
		7.1	Planning of product realization
		7.2	Customer-related processes
		7.2.1	Determination of requirements related to the product
		7.2.2	
		7.3	Review of requirements related to the product
		7.3.1	Design and development
		7.3.2	Design and development planning
		7.3.3	Design and development inputs
		7.3.4	Design and development outputs
		7.3.5	Design and development review
		7.3.6	Design and development verification
		7.3.7	Design and development validation
		7.4	Control of design and development changes
		7.4.1	Purchasing
		7.4.2	Purchasing process
		7.4.3	Purchasing information
		7.5	Verification of purchased product
		7.5.1	Production and service provision
		7.5.3	Control of production and service provision
		7.5.4	Identification and traceability
		7.5.5	Customer property
		7.5.2	Preservation of product
			Validation of processes for production and service provision
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking and corrective action	4.5	8	**Measurement, analysis and improvement**
Monitoring and measurement	4.5.1	7.6	Control of monitoring and measuring devices
		8.1	General
		8.2	Monitoring and measurement
		8.2.1	Customer satisfaction
		8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
		8.4	Analysis of data
Nonconformance and corrective and preventive action	4.5.2	8.3	Control of nonconforming product
		8.5.2	Corrective action
		8.5.3	Preventive action
Records	4.5.3	4.2.4	Control of records
Environmental management system audit	4.5.4	8.2.2	Internal audit
Management review	4.6	5.6	Management review
		5.6.1	General
		5.6.2	Review input
		5.6.3	Review output

Annex B
(informative)

Correspondence between ISO 9001:2000 and ISO 9001:1994

Table B.1 - Correspondence between ISO 9001:1994 and ISO 9001:2000

ISO 9001:1994	ISO 9001:2000
1 Scope	1
2 Normative reference	2
3 Definitions	3
4 Quality system requirements [title only]	
4.1 Management responsibility [title only]	
4.1.1 Quality policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization [title only]	
4.1.2.1 Responsibility and authority	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management representative	5.5.2
4.1.3 Management review	5.6.1 + 8.5.1
4.2 Quality system [title only]	
4.2.1 General	4.1 + 4.2.2
4.2.2 Quality system procedures	4.2.1
4.2.3 Quality planning	5.4.2 + 7.1
4.3 Contract review [title only]	
4.3.1 General	
4.3.2 Review	5.2 + 7.2.1 + 7.2.2 + 7.2.3
4.3.3 Amendment to a contract	7.2.2
4.3.4 Records	7.2.2
4.4 Design control [title only]	
4.4.1 General	
4.4.2 Design and development planning	7.3.1
4.4.3 Organizational and technical interfaces	7.3.1
4.4.4 Design input	7.2.1 + 7.3.2
4.4.5 Design output	7.3.3
4.4.6 Design review	7.3.4
4.4.7 Design verification	7.3.5
4.4.8 Design validation	7.3.6
4.4.9 Design changes	7.3.7
4.5 Document and data control [title only]	
4.5.1 General	4.2.3
4.5.2 Document and data approval and issue	4.2.3
4.5.3 Document and data changes	4.2.3
4.6 Purchasing [title only]	
4.6.1 General	
4.6.2 Evaluation of subconractors	7.4.1
4.6.3 Purchasing data	7.4.2
4.6.4 Verification of purchased product	7.4.3

Table B.1 - Correspondence between ISO 9001:1994 and ISO 9001:2000 *(continued)*

ISO 9001:1994	ISO 9001:2000
4.7 Control of customer-supplied product	7.5.4
4.8 Product identification and traceability	7.5.3
4.9 Process control	6.3 + 6.4 + 7.5.1 + 7.5.2
4.10 Inspection and testing [title only]	
4.10.1 General	7.1 + 8.1
4.10.2 Receiving inspection and testing	7.4.3 + 8.2.4
4.10.3 In-process inspection and testing	8.2.4
4.10.4 Final inspection and testing	8.2.4
4.10.5 Inspection and test records	7.5.3 + 8.2.4
4.11 Control of inspection, measuring and test equipment [title only]	7.6
4.11.1 General	7.6
4.11.2 Control procedure	
4.12 Inspection and test status	7.5.3
4.13 Control of nonconforming product [title only]	
4.13.1 General	8.3
4.13.2 Review and dispositioning of nonconforming product	8.3
4.14 Corrective and preventive action [title only]	
4.14.1 General	8.5.2 + 8.5.3
4.14.2 Corrective action	8.5.2
4.14.3 Preventive action	8.5.3
4.15 Handling, storage, packaging, preservation & delivery [title only]	
4.15.1 General	7.5.5
4.15.2 Handling	7.5.5
4.15.3 Storage	7.5.5
4.15.4 Packaging	7.5.5
4.15.5 Preservation	7.5.1
4.15.6 Delivery	
4.16 Control of quality records	4.2.4
4.17 Internal quality audits	8.2.2 + 8.2.3
4.18 Training	6.2.2
4.19 Servicing	7.5.1
4.20 Statistical techniques [title only]	
4.20.1 Identification of need	8.1 + 8.2.3 + 8.2.4 + 8.4
4.20.2 Procedures	8.1 + 8.2.3 + 8.2.4 + 8.4

Table B.2 - Correspondence between ISO 9001:2000 and ISO 9001:1994

ISO 9001:2000	ISO 9001:1994
1 Scope	**1**
1.1 General	
1.2 Application	
2 Normative reference	**2**
3 Terms and definitions	**3**
4 Quality management system [title only]	
4.1 General requirements	4.2.1
4.2 Documentation requirements [title only]	
4.2.1 General	4.2.2
4.2.2 Quality manual	4.2.1
4.2.3 Control of documents	4.5.1 + 4.5.2 + 4.5.3
4.2.4 Control of records	4.16
5 Management responsibility [title only]	
5.1 Management commitment	4.1.1
5.2 Customer focus	4.3.2
5.3 Quality policy	4.1.1
5.4 Planning [title only]	
5.4.1 Quality objectives	4.1.1
5.4.2 Quality management system planning	4.2.3
5.5 Responsibility, authority and communication [title only]	
5.5.1 Responsibility and authority	4.1.2.1
5.5.2 Management representative	4.1.2.3
5.5.3 Internal communication	
5.6 Management review [title only]	
5.6.1 General	4.1.3
5.6.2 Review input	
5.6.3 Review output	
6 Resource management [title only]	
6.1 Provision of resources	4.1.2.2
6.2 Human resources [title only]	
6.2.1 General	4.1.2.2
6.2.2 Competence, awareness and training	4.18
6.3 Infrastructure	4.9
6.4 Work environment	4.9
7 Product realization [title only]	
7.1 Planning of product realization	4.2.3 + 4.10.1
7.2 Customer-related processes [title only]	
7.2.1 Determination of requirements related to the product	4.3.2 + 4.4.4
7.2.2 Review of requirements related to the product	4.3.2 + 4.3.3 + 4.3.4
7.2.3 Customer communication	4.3.2
7.3 Design and development [title only]	
7.3.1 Design and development planning	4.4.2 + 4.4.3
7.3.2 Design and development inputs	4.4.4

Table B.2 - Correspondence between ISO 9001:2000 and ISO 9001:1994 *(continued)*

ISO 9001:2000	ISO 9001:1994
7.3.3 Design and development outputs	4.4.5
7.3.4 Design and development review	4.4.6
7.3.5 Design and development verification	4.4.7
7.3.6 Design and development validation	4.4.8
7.3.7 Control of design and development changes	4.4.9
7.4 Purchasing [title only]	
7.4.1 Purchasing process	4.6.2
7.4.2 Purchasing information	4.6.3
7.4.3 Verification of purchased product	4.6.4 + 4.10.2
7.5 Production and service provision [title only]	
7.5.1 Control of production and service provision	4.9 + 4.15.6 + 4.19
7.5.2 Validation of processes for production and service provision	4.9
7.5.3 Identification and traceability	4.8 + 4.10.5 + 4.12
7.5.4 Customer property	4.7
7.5.5 Preservation of product	4.15.2 + 4.15.3 + 4.15.4 + 4.15.5
7.6 Control of monitoring and measuring devices	4.11.1 + 4.11.2
8 Measurement, analysis and improvement [title only]	
8.1 General	4.10 + 4.20.1 + 4.20.2
8.2 Monitoring and measurement [title only]	
8.2.1 Customer satisfaction	
8.2.2 Internal audit	4.17
8.2.3 Monitoring and measurement of processes	4.17 + 4.20.1 + 4.20.2
8.2.4 Monitoring and measurement of product	4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2
8.3 Control of nonconforming product	4.13.1 + 4.13.2
8.4 Analysis of data	4.20.1 + 4.20.2
8.5 Improvement [title only]	
8.5.1 Continual improvement	4.1.3
8.5.2 Corrective action	4.14.1 + 4.14.2
8.5.3 Preventive action	4.14.1 + 4.14.3

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講演Ⅳ　小林　敏孝

モンゴル乳業に関する一私見（セミナー講演要旨）

（1）はじめに

乳業とは（1）牛乳の中にある細菌を殺すことと,（2）人に有用な菌を乳中で生かすことおよび（3）牛乳成分を目的に応じて分離する３つの仕事から成り立ってます。

これが成立するためには，消費者の健康とその向上を目的として農場，原乳や製品の輸送業者，乳製品の製造工場，製品の販売する人および製品の安全性を検査する機関が全体として動くシステムが必要で，これには政府の力も必要になりますが，一番重要な原動力となるのは乳製品を製造する企業とこれに関連する機関であります。

また特にモンゴルにおいては農牧民の生活確保とその向上を図ることは至上命令と考えねばなりません。なぜならば，モンゴルは農業国を目指しながら，工業化を進めなければならないからであります。かかる観点から世界の乳業の発展方向と経済発展の著しい中国乳業の状況について解説する上で，私が数日間滞在していた知見からモンゴル乳業に対する２，３の提言をしたいと思います。

これは盲目の老人が初めてであった象の腹を手で触れて「象とは何なのか」を言うのと同じで間違えだらけだと思いますが，あえて言っておきたい。

（2）世界の乳業

世界的に見れば乳業界も大きな経済変化のうねりの中で変化していますが，その背景には技術の進歩と経済の国際化，社会の巨大化，人口増加，中央および東ヨーロッパ等の計画経済から市場経済への転換とスケールの拡大があります。乳生産量は５億トンに達し，人口も50億人を超えています。消費量は平均で80kg/年・人，先進国は200kg/年・人であります。ここモンゴルでは130kg/・人で，昔はもっと消費されていたといわれております。

先進国の間では生産地と消費地との差から乳製品は輸出入のターゲットとなり，「白い黄金」といわれていますが，食習慣から見て，モンゴルでは「白い肉」ではないかと思います。

そして世界全体としてはヨーグルトとチーズの増産と乳製品の機能性の追及が鋭意進められているのが現状であります。

（3）中国の乳業

改革解放後の中国の生活水準は上昇し，それに伴い食糧消費は急増しています。このため中国は酪農農業を重要視し，東北を中心にその振興を図っています。

乳牛は500万頭，乳製品は50万トンです。主要生産地は黒龍江省で190万トン，内蒙古で60万トンであります。乳製品50万トンの内，35万トンは粉乳で，その他，低温殺菌乳，UHT乳（消費増加），ヨーグルト（セットヨーグルト，攪拌ヨーグルト），還元乳，粉乳（加糖粉乳が主体で，その他母乳化粉乳，フォローアップミルク，老人用ミルク），バター，イラールで少量生産），チーズ（ナチュラルチーズとプロセスチーズ）が生産され，チーズについては今後ピザ用のモッザレラチーズが期待されています。

乳の消費量は4.5kg/年・人で，世界的に見ても極めて低く，乳質も搾乳，輸送，工場受け入れ，いずれの段階でもまだ良くなく，品質検査体制も不十分でありますが急送に改善が進められており，乳業企業も約1000に達しています。大型企業としては，上海光明，内蒙古伊利，石家庄三鹿，北京三元食品，ハルピン金星乳業，黒竜江乳業などがあり，これに対応して設備メーカーも60社程度に増加し，上海，黒竜江を中心に発達しております。乳製品の製造訓練センターもハルピン，上海，北京，フホホトなど五箇所あり，分析機器メーカーも急速に発展しており，モンゴルにとって極めて留意すべき国になっています。

（4）モンゴルの乳業

以上の状況からモンゴルを見ますと，ソビエト支援体制の崩壊はポーランド，チェコ，ハンガリーなど東ヨーロッパでも見られる大型工場の老朽化，稼働率の低下につながっておりますが，このモンゴルにおいても同様な現象が発生しております。それに変わって小型工場が竹の子のごとく芽を吹き出しているのが現在のモンゴル乳業と思われます。これら乳業工場を見て気のついた点をいくつか申し上げたい。

1）微生物汚染

工場を見て共通に感じられるのは，清潔であること，これはモンゴル人の習慣や気質もさることながらロシアの伝えた遺産ではないかと思います。農場を見ても同じであります。どの牛乳缶もステンレスで，へこみもあまりなく，水洗が行き届いており，また工場内も整理整頓がかなり行き届いていて，床も壁も清潔に見えます。しかし，重要な点を忘れています。細菌汚染防止の点からは核拡散防止原則と同じで，「使わない，持ち込まない，持ち出さない」ことが重要であります。製造室出入りの場合の手洗浄，消毒と作業靴の取替え，消毒がほとんどの工場でなされてはいないので，これは直さなければなりません。また，牛乳缶の持ち込み場所と製造室の隔離が十分されておらず，牛乳缶も洗浄後，殺菌して農場に返却すべきであります。

そして重要なのは都市部における未殺菌乳の販売がなされておりますが，これは早急に禁止すべきであります。

2）殺菌，冷却時間の短縮化

品質を維持するには加熱冷却時間の短縮が重要でありますが，少量多品種生産の場合には収率の点からバッチ式をとらざるを得ません。その場合に問題になるのは攪拌でありますが，大部分の工場は手攪拌であります。モーター攪拌機にも移動式のものがあり，ひとつの攪拌機で複数のタンクに対応できます。各企業が一括して購入すれば安く手に入るはずです。重要なことは各企業は競争するとともに協調することが必要であります。このことは農場の冷却保管についてもいえます。集乳センターを共同運営する組合を設立すべきであります。このセンターで法的規制がないのであれば，65度殺菌して大部分の汚染菌を死滅させるサーミゼイションを行えば，遠距離輸送も可能になるでしょう。現在の工場受け入れ菌数106cfu/mlを105cfu/mlにするのは不可能ではありません。

3）ヨーグルトスターターの集中生産

多くの工場がクリスチャンハンゼンやロシアからスターターを輸入して用いてます。各企業が共同して特定の機関（技術大学，食品研究所等）に委託生産されるべきであります。オランダNIZO研究所もこのシステムを採用しておりますし，私のいた明治乳業（ヨーグルト20万トン）では社内の10工場に対して一箇所でスターターを集中生産して配布し，一定品質のヨーグルトを生産できるようにしております。バルク用スターターであれば特に高価なアセプティックな菌体分離機を用いずにアセプティックファーメンター，クリーンベンチ，小型ガラス瓶の乾熱滅菌機とフリーザーがあれば可能であります。このようにして品質の良い乳製品が確保されれば，消費は伸び，乳生産量も増えて農民の生活も向上し，乳の自給率も上がることになります。

乳生産量の少ない現段階では，外貨持ち出しは極力避けて乳の不足分は乳原料（全粉，脱粉）に絞り，最終商品の乳製品の輸入は控えることが必要であります。そのためにこそ，国内消費商品の品質アップが重要で先に述べたスターターもその一環であります。

4）乳業技術の発展

ヨーグルトの機能性（免疫賦活性etc）を高める素材開拓，ラクターゼ処理技術による乳の甘味を増して100％輸入している砂糖は使用しない方策とか遠距離輸送のためのRO濃縮技術の展開など多くの検討テーマがあります。

（5）結語

以上述べましたように農民と乳業界，研究機関，政府が一致協力して乳製品の品

質向上に努め，よって乳の自給率を高めることがさしあたっての重要目標であり，HACCP，ISOの考え方，思想を十分生かしてこの目標に努力していただきたい。とにかく乳業関係の皆さんは急がねばならないのであります。そしてやがては自分で消費する「白い肉」から脱却して，乳製品を輸出して「白い黄金」に転換できるようにしようじゃありませんか。

以上

10. 結語

モンゴルの酪農，及び乳業にとっても又モンゴルの消費者にとっても，重要なことは輸入乳製品をいかにして縮少させ，自国乳製品をいかにして増大させるかである。

さもなくば，かつて中国の“清”が，くず茶を固めたレンガ茶（今でも牛乳に塩と茶を入れて飲んでいる）をビタミンCの不足しているモンゴルに売り込み膨大な利益を上げ，逆にモンゴル人はこれを買うため大変な苦労を舐めたと同じ現象が始まっているからである。

そのためには乳製品の輸入関税を現在の０％から脱却させる政策が望まれるが（原料脱粉，全粉は乳生産量が少ない現時点では止むを得ないが）その前に未殺菌乳の販売禁止と乳製品の品質改善及びこれに必要な乳質改善が不可欠である。

又乳製品企業が群雄割拠している現時点では，新製品開発による差別化と企業統合による新規設備導入による製造の合理化，改善が必要である。

セミナー新聞広告

FROM：Daily　newspaper

БИЗНЕС ЭРХЛЭГЧ, БАЙГУУЛЛАГУУДЫН АНХААРАЛД

Монголын Үндэсний Худалдаа аж үйлдвэрийн танхим нь ***Япон улсын Хүнсний бүтээгдэхүүн үйлдвэрлэгчдийн холбоо (Japan Food Industry Center), Японы Олон улсын хамтын ажиллагааны нийгэмлэгтэй (Japan International Cooperation Agency)*** хамтран ***малын сүү, саалийн ашиглалтыг сайжруулах, боловсруулалтын түвшинг дээшлүүлэх сүү, сүүн бүтээгдэхүүний үйлдвэрлэл, хангамжийг нэмэгдүүлэх зорилгоор «Монголын сүүн бүтээгдэхүүн» хөтөлбөр*** хэрэгжүүлж байгаа билээ.

Энэхүү хөтөлбөрийн хүрээнд хүнсний бүтээгдэхүүний хадгалалт, хамгаалалт, чанарын хяналт **(HACCP, ISO 9000),** ферментжүүлсэн бүтээгдэхүүнийг хөгжүүлэх сэдэвт сургалт семинар **2003 оны 10-р сарын 30-нд МҮХАҮТ-ын (Засгийн газрын 11-р байр) хурлын дугуй зааланд** зохион байгуулах тул Та бүгдийг өргөнөөр оролцохыг урьж байна.

Семинарт оролцох байгууллага, хувь хүмүүс **2003 оны 10-р сарын 28-ны** дотор **323974, 99278874** тоот утсаар бүртгүүлнэ үү.

Жич: Семинар болон хүлээн авалт төлбөргүй.

БИЗНЕС ЭРХЛЭГЧ, БАЙГУУЛЛАГУУДЫН АНХААРАЛД

Монголын Үндэсний Худалдаа аж үйлдвэрийн танхим нь ***Япон улсын Хүнсний бүтээгдэхүүн үйлдвэрлэгчдийн холбоо (Japan Food Industry Center), Японы Олон улсын хамтын ажиллагааны нийгэмлэгтэй (Japan International Cooperation Agency)*** хамтран ***малын сүү, саалийн ашиглалтыг сайжруулах, боловсруулалтын түвшинг дээшлүүлэх сүү, сүүн бүтээгдэхүүний үйлдвэрлэл, хангамжийг нэмэгдүүлэх зорилгоор «Монголын сүүн бүтээгдэхүүн» хөтөлбөр*** хэрэгжүүлж байгаа билээ.

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V 資　　料

モンゴル国法律

1999年10月7日
ウランバートル市

食品法

(改訂版)

第1章 総則

第1条　法律の目的

1.1. この法律の目的は国民の食品需要、食品安全性を保障し、食品の生産およびサービスに関する政府、個人および法的主体の間の関係を調整することである。

第2条　食品立法

2.1. 食品立法は、モンゴル国憲法、この法律、およびそれらに従って出された他の法令から成る。

2.2. モンゴルの国際条約にはこの法律と異なる規定がされていれば国際条約に従う。

第3条　定義

3.1. この法律において使用される言葉は以下のように定義される。

3.1.1.「食品」とは、人体の成長・発展およびエネルギー損失を補うために必要となる食品原材料、食品中間財、食べ物、飲料品および飲料水を意味する。

3.1.2.「食品安全性」とは、 食品の品質および衛生の適切な基準が満たされていることを意味する。

3.1.3.「食品衛生」とは、食品の生産およびサービス業務を行う工程において食品安全性を満たす条件を意味する。

3.1.4.「食品添加物」とは、食品に特殊性を与えるために技術的に利用される物質と混合物を意味する。

3.1.5「特定の食品項目」とは、人の仕事および人体の特性に適合させた食品、又は治療用につくられた食品を意味する。

3.1.6. 「戦略的食品」とは、モンゴル人の食生活に使い慣れしんだ、人体の生理的な要求に必要な肉、穀物、飲料水および塩を意味する。

3.1.7.「食品強化」とは、その食品に含まれない又は生産工程において失われる人間の健康

に必要なビタミン、アミノ酸および超小形素子を特殊および標準的な技術によって追加することを意味する。

3.1.8「食品安全性基準」とは、 食品に含まれる細菌、菌、物理的な及び化学汚染の認められる最高水準を意味する。

3.1.9「食品安全性の第一次基準」とは、人間の感覚または敏速な検査方法によって定義される衛生学的水準を意味する。

第２章 国および地方の行政機関の権限

第４条　国会の権限

4.1.食品問題に関して国会は以下の権限を有する。

4.1.1.国民の食品供給、食品安全性に関する国家政策を策定し、その執行を監視する。

4.1.2.政府の提案に基づいて戦略的食品の生産者に対して国家の資金政策、融資政策、税政策によって支援する。

4.1.3.国家予備食品の種類の規定、変更する。

第５条　政府の権限

5.1.食品問題に関して政府は以下の権限を有する。

5.1.1.国の予備食品を調達する、保管する、新しくする、使用する、補給する規則を定め、必要な資金を各年の国家予算に反映させる。

5.1.2.国民の飲料水源を探鉱する、水資源、井戸を増加させる、浄水政策を規定し、執行する。

5.1.3.食品安全性基準を規定し、輸入食品に対する監視規則を定める。

5.1.4.飲料水源および水道設備を保護する、それに対する管理体制・規則を定める。

5.1.5.戦略的食品生産者に食品を発注し、割引貸付を行なう。

5.1.6.日常食品の食品強化の生産者を支援する。

5.1.7.国民の実質食品需要、食品の品目、食品の構成要素および栄養成分の適切の割合、そして特定の食品項目利用者の食品ノルマ補給に対して分析し、その結果を国会に報告する。

5.1.8.特定の許可によって生産される食品の生産者に対して法定に従って許可を与える。

5.1.9.食品安全性に対する管理・規則を定める。

第６条　中央行政機関の権限

6.1.食品問題に関して中央行政機関は以下の権限を有する。

6.1.1.食品の供給量、安全性を考慮した上で当年度に輸入および輸出する家畜、戦略的食品の項目、数量に関して公衆に公表する。

6.1.2. 食品の生産・サービス業務の技術および植物性原材料、動物性原材料の健康・衛生に関する基本的な規則、基準、条件を定める。
6.1.3. 特定の許可によって生産される食品の生産を行なう申請を規定に従って検討し、政府に提案する。
6.1.4. 食品の栄養分を増加させる、生産量を増加させる、伝統および近代の技術を導入する政策を執行する。
6.2. 健康に関する問題を担当する中央行政機関は食品問題に関して以下の権限を有する。
6.2.1.食品とその生産に必要な設備の生産者、関連するサービス業者に対して健康、衛生、安全性の条件を満たすための基本的な規則、手引き、基準を承認する。
6.2.2.農業、食品生産に利用されている殺虫剤、薬、肥料、放射性物質、重金属品、他の化学物質、マイクロ有機体、食品添加物および他の混合物の認められる最高水準を設定し、国家基準に追加する。
6.2.3. 食品強化に必要な超小形素子の適切な基準を定める。

第７条　アイマッグ、首都、ソム、町の市民代表議会、知事の権限
7.1. アイマッグ、首都、ソム、町の市民代表議会は各区域市民の食品安全性に関する政策、計画を承認し、その実行状況を監視する。
7.2. アイマッグ、首都、ソム、町の知事は以下の権限を有する。
7.2.1. その区域市民の食品安全性にする政策、計画を立案し、その区域の市民代表議会に提案する。
7.2.2. その区域の市民の食品安全性にする政策、計画の執行、市民の実質消費状況をその区域の市民代表議会で紹介し、関連する問題を担当機関に報告する。
7.2.3. 個人および法的主体は食品の生産・サービス業務を行なう環境づくりを支援する。
7.2.4. 食品生産者、関連するサービス業者の周辺に食品を汚染させる影響のある生産、サービスを行なうことを国家監視官の検査報告に基づいて禁止する。
7.2.5. 市民に飲料水を供給する行動を組織し、飲料水源、水道供給施設、水道管、設備およびその他の設備の利用、保護を管理する。
7.3. アイマック、首都は特定量の予備食品を確保することができる。

第３章 食品品質、衛生保障

第８条　食品生産者・サービス業に従事している主体の権限
8.1. 食品の生産、サービスに従事している主体は以下の権限を有する。
8.1.1. 食品サンプルを検査する権限を持つ検査所を選択する。
8.1.2. 生産、サービスに関する検査報告、取られた処置に関して国家監視官に対して説明を求める、また説明する、苦情を申し出る。

第９条　食品の生産・サービス業に従事している主体の責務、それに対する条件、禁止事項

9.1. 食品の生産・サービス業に従事している主体は以下の責務を有する。

9.1.1. 食品の生産・サービス業務の技術、基準および衛生条件に従って行なうこと、製品、サービスの品質および衛生安全性を保障する。

9.1.2. 食品生産・サービス業に従事している主体は、営業を開始する前および営業中にこの法律の 9.1.1 の規定を満たしているという専門監視機関の検査を受け証明書を受ける。

9.1.3. 食品の生産・サービス業に従事している主体は、消費者の要求に従って消費者に 9.2.1、9.2.3、9.6 に規定された書類を提示する。

9.2. 家畜・動物性原材料、植物性原材料および家畜・動物性製品、植物性製品の生産・サービスに従事している主体は以下の条件を満たす。

9.2.1. 家畜・動物性食品原材料、植物性食品原材料を生産するときに当区域の獣医および植物の検疫権を持つ機関の検査を受け、証明書を受ける。

9.2.2. 食品生産の内部検査をする場合には権限を有する機関の適切な許可を受る。

9.2.3. 新しく生産している食品を基準、衛生、健康の条件を満たしているという専門監視機関の証明書を受け取った後に販売する。

9.2.4. 食品生産・サービスに利用するマイクロ有機体、化学物質、薬、肥料、殺虫剤および放射性物質を衛生、疫学、獣医、植物の検疫の権限を持つ機関の検査を受け、証明書を受け、特定の規定に従って国に登録する。

9.2.5. 食品を生産する、保存する、輸送する専門の車、装置、用具、容器・包装材、消毒物質は品質、衛生条件を満たす。

9.2.6. 食品を品質、衛生、健康の条件に従って容器詰めし、ラベルを貼り、ラベルに栄養値、成分、利用方法、保存期限、注意点などを表示する。

9.2.7. 食品の生産・サービス業務用の建物を新しく建設する、増設する、リフォームする、設備を新しく設置する仕事を専門監視機関と合意した設計図、証明書に従ってする。

9.3. 個人および法的主体は食品を輸入するために以下の条件を満たす。

9.3.1. 食品の品質、衛生、安全性の水準は、国際基準および国家基準を満たす。

9.3.2. 家畜、動物、鳥の生の肉、脂身、内臓、副産物、魚、その他の原材料、卵、植物、種、植物性原材料、特定の食品、アルコール飲料類を輸入する場合には、関連する専門機関に 20 仕事日以内に報告し、当輸出国の権限を持つ機関によって発行された証明書、契約に基づいて前もって許可を受ける。

9.3.3. 食品サンプルに衛生安全性の検査を受け、証明書を受ける。

9.4. 食品生産・サービス業に従事している主体の以下の活動を禁止する。

9.4.1. 安全性の条件に関する専門監視機関の証明書のない食品を販売する、生産用に利用すること。

9. 4. 2. 汚染の水準が衛生、安全性の認められた最高基準値を上回る食品を生産する、販売すること。
9. 4. 3. 獣医、植物検疫検査所によって検疫が証明されてない家畜・動物性の原材料、製品、種、植物、植物性原材料、製品を販売すること。
9. 5. 食品生産、サービスの技術者は専門家であること。
9. 6. 食品生産・サービス業を行う個人は健康診断を受け、証明書を受ける

第１０条 国家予備食品

10. 1. 自然災害、大規模な工場事故、非常に危険な伝染病および他の突然の災害が起こり、食品供給の深刻な困難が生じた場合および軍の動員に利用する目的で国家予備食品をする。
10. 2. 国家予備食品には、肉、乾燥肉、缶詰、動物性および植物性の油、穀物、穀物の種、小麦粉、様々な米、角砂糖、茶葉、粉ミルク、塩、エチルアルコールなどが含まれる。
10. 3. 政府は、国家予備食品の運動、品質に関して国会、国家安全保障委員会に毎年報告する。

第４章 食品の安全性に対する監視

第１１条 食品の安全性に対する監視

11. 1. 食品安全性に対する監視は食品を調達する、加工する、生産する、容器詰めする、輸送する、販売するおよび食品廃棄物のリサイクルの段階において食品安全性の条件を満たす目的に利用される。
11. 2. 食品安全性に対する監視は以下の範囲におよぶ。
11. 2. 1. 食品汚染の認められた基準および必ず必ず従う基準の執行。
11. 2. 2. 食品を生産する建物、設備、周囲の衛生、健康の条件。
11. 2. 3. 輸入食品の安全性の基準、条件の執行。
11. 2. 4. 家畜・動物および家畜・動物性原材料、家畜・動物性製品を都市部に入れる、屠殺するおよびそれを利用して生産、サービスをする場合に実施される獣医、健康、衛生の条件、その執行。
11. 2. 5. 種、植物、植物性原材料、植物性製品を輸送する、生産する、サービスする時に実施する植物の検疫条件、その実施状況。

第１２条 食品安全性に対する国家監視制度

12. 1. 食品安全性に対する監視を全国的に専門監視機関、地方では監視局が担当する。
12. 2. 国家監視最高官、監視上官、監視官を国家監察・検視法（State Inspection and Auditing Law）の第１章 21 条の 2,3,4,6 の規定に従って任命し、解任する。
12. 3 専門監視機関は以下の権限を有する。

12.3.1.食品安全性の基準を規定し、食品を輸入する許可を発行する。
12.3.2.アイマック、首都、国境の監視局に専門的、方法論的な指導を与え、食品生産者・サービス業者に対して研修を実施する。
12.3.4.品質、衛生条件を満たしてない食品、それを生産する設備の輸入、輸出を禁止する。
12.3.5.食品の品質、衛生安全性、国民の健康に与える影響を分析し、その結果に基づいて判断し、対策に関する提案を作成し、関連する機関に提出する。
12.3.6.食品衛生に関するデータベースを作成する。
12.4.常時開通国境地には食品安全性基準を、他の開通国境地には食品安全性第一次基準を検査できる検査所を有する監視局を設置する。

第１３条 食品安全性に対する監視官の権限
13.1.食品安全性に対する検査を食品の生産技術、健康、種、植物、検疫、獣医、衛生に関する各専門的な国家監視官が以下の方針で実施する。
13.1.1.衛生、疫学研究の監視官は、食品生産者、サービス業者の健康、生産・サービスを行っている建物、周囲、生産工程の複雑な点、利用可能になった食品の衛生、清潔の安全性を検査する。
13.1.2.獣医の監視官は、市場で販売されているおよび食堂、加工工場で原材料として利用されている家畜、動物、その肉、脂身、内臓肉、副産品、魚、牛乳、乳製品、生卵、家畜・動物性原材料および家畜・動物性製品の生産、サービス業務を行っている建物、周囲、生産工程の複雑な点、利用可能になった食品の衛生、清潔の安全性を検査する。
13.1.3.植物検疫の監視官は、野菜、果物、植物性原材料および野菜倉庫、食堂の野菜保管場の衛生、清潔の安全性を検査する。
13.1.4.食品生産、サービス監視官は、食品、その生産設備を生産する、設備を利用する為に必要な技術基準、実施条件を検査する。
13.1.5.基準検査保障の監視官は、食品設備に関する書類、生産設計図の作成、実施から食品を消費するまでの生産、サービスのすべての段階における国家基準の執行を検査する。
13.2.国家監視官は以下の権限を有する。
13.2.1.食品の品質、衛生安全性に関する法令、これに伴う権限有する機関の規定を執行させ、発見された問題を解決し、違反者に対して罰則を課す。
13.2.2. 食中毒、その感染原因を解明しそれを阻止し、即急に公表する。
13.2.3.この法律の 9.1.2、9.2.4 の規定の結果を５仕事日以内に、保存食品の検査、その結果を 20 仕事日以内に提出する。
13.3.食品安全性に対して検査をする監視官の以下の活動を禁止する。
13.3.1.いかなる個人、法的主体の私的利益のため、又は彼らに有利な決断をする。
13.3.2.検査中に得た秘密を漏らす。
13.3.3. 権限を悪質に利用する、その用具を目的外に利用する。

第１４条 食品の衛生安全性に対する監視、保証

14.1.食品の生産・サービス業に従事している主体の食品サンプルに対して衛生、健康、安全性、疫学、獣医、植物検疫の検査所が検査を実行する。

14.2.検査所の検査結果に基づいて国家監視上官、および監視最高官が結論を出し、保証する。

14.3. 中央基準計測機関が食品安全性を検査する検査所に対して適切な規定に従って委任状を発行する。

第１５条 食品の衛生、健康、安全性に対する部外者の監視

15.1.検査委任状を受けた法的主体は食品の衛生、品質の安全性に対して部外者として監視することができる。

15.2.食品の部外者検査機関に対して専門監視機関が委任状を発行する。

第１６条 食品の健康安全性に対する内部および公共監視

16.1.生産、サービス業に従事している主体は特別な権限を持つ機関が規定した一般的な条件に適合する生産工程、衛生規則を承認し、その基準、衛生条件の執行に対して内部監視を行う。

16.2.個人、非政府機関が食品安全性に対して監視し、明らかになった問題点を行政府機関および検査権限を有する機関、役員に報告し、マスコミを通して公衆に警告する。

第5章 その他

第１７条 法令に違反した者に対する罰則

17.1.食品に関する法令に対する違反は刑事的な責任を追及するほどではない場合に、違反者に対して国家監視官および裁判官は以下の罰則を課す。

17.1.1.この法律の9.1.1、9.1.3、9.2.5、9.2.6、9.5、9.6に違反した個人に対して8000-15000、役人に対して10000-20000、法的主体に対して60000-150000トゥグリクの罰金を課す。

17.1.2.この法律の9.1.2、9.2.1、9.2.2、9.2.3、9.2.4に違反した個人に対して15000-30000、役人に対して20000-40000、法的主体に対して150000-200000トゥグリクの罰金を課す。

17.1.3.この法律の9.2.7、9.3、9.4に違反した個人に対して30000-50000、役人に対して40000-60000、法的主体に対して200000-250000トゥグリクの罰金を課す。

17.1.4.人間の健康、生命に害を与えることが検査所の検査によって立証された食品を回収し処理して、国が違法的な所得を没収する。

17.2.違反者はこの法律の17.1.2の規定に違反する行為を1年以内に再び起こしたことによって生産・サービスを継続することは食品安全性に悪影響を与えていれば、裁判官はそ

の個人、役人、法的主体のその工場、サービスを運営する許可を6ヶ月間停止する。

第１８条 苦情を申し出る

18.1. この法の 17 条の規定によって課された罰則は不適切と考えている個人、法的主体は特定の規定に基づいて苦情を申し出ることができる。

モンゴル国会議長　　R. ゴンチグドルジ

モンゴル国政府

農業産業省

「白い革命」

国家ガイドライン

ウランバートル 1999 年

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