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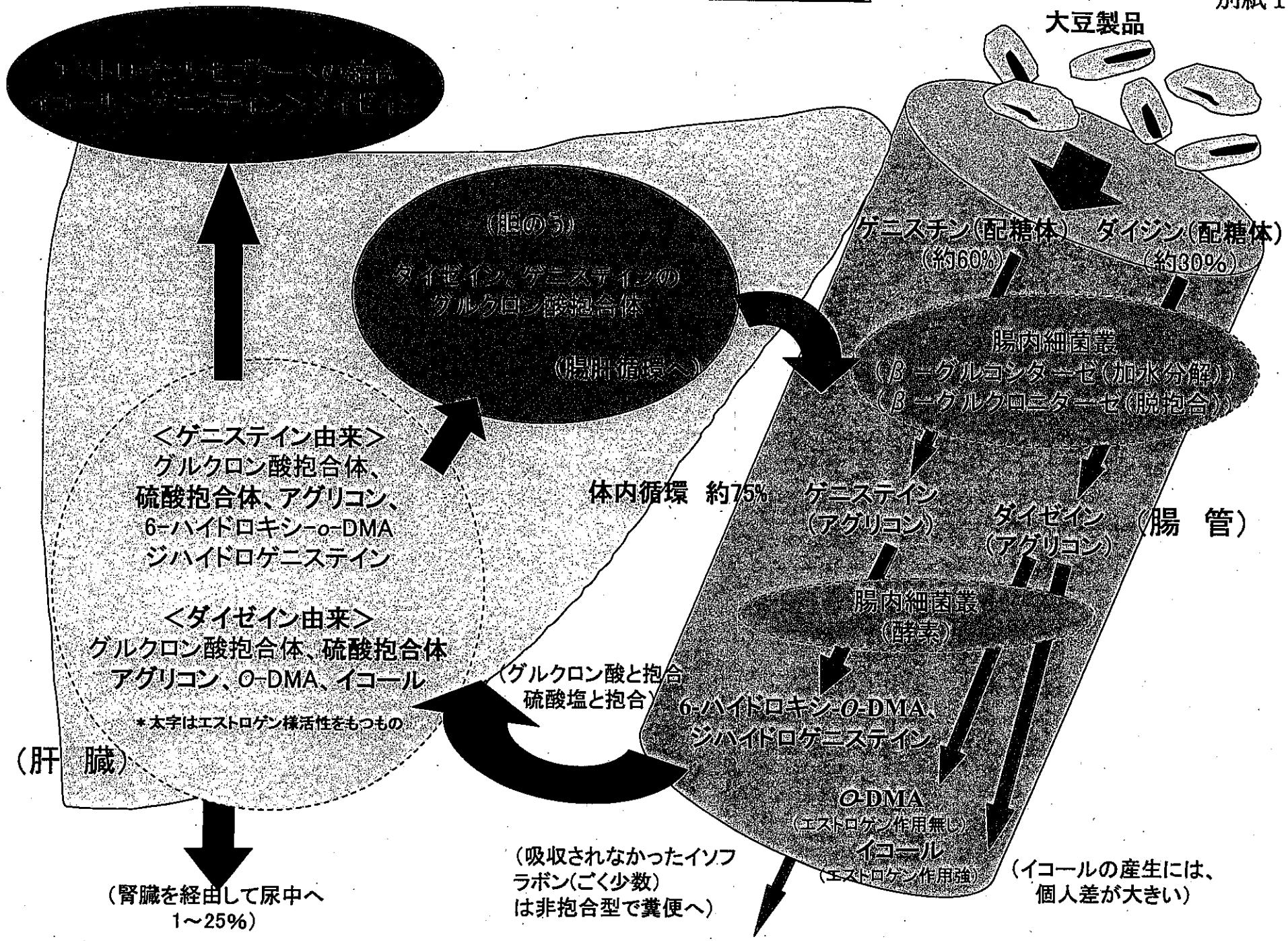
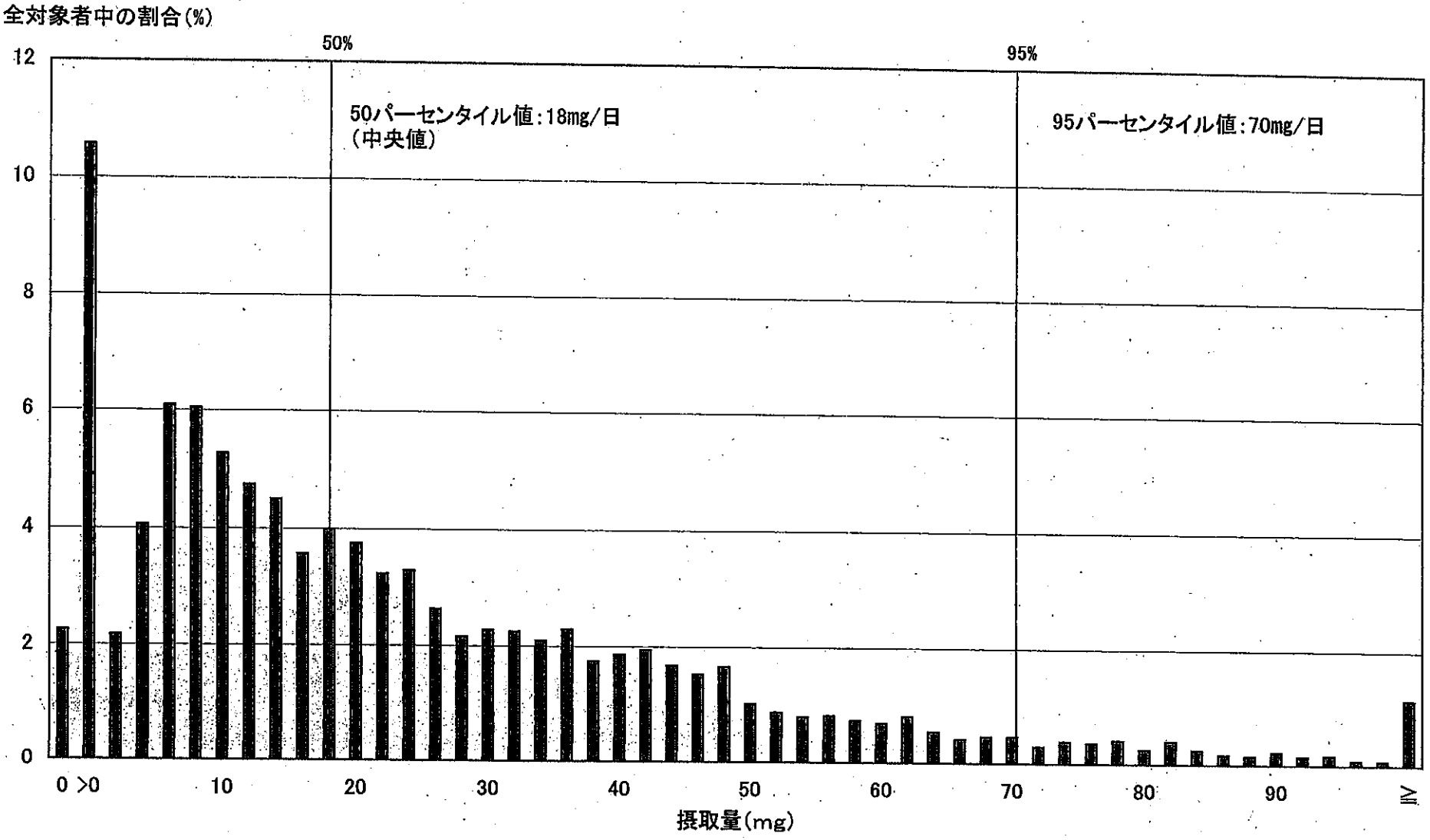
大豆イソフラボンの体内動態フロー図

別紙１



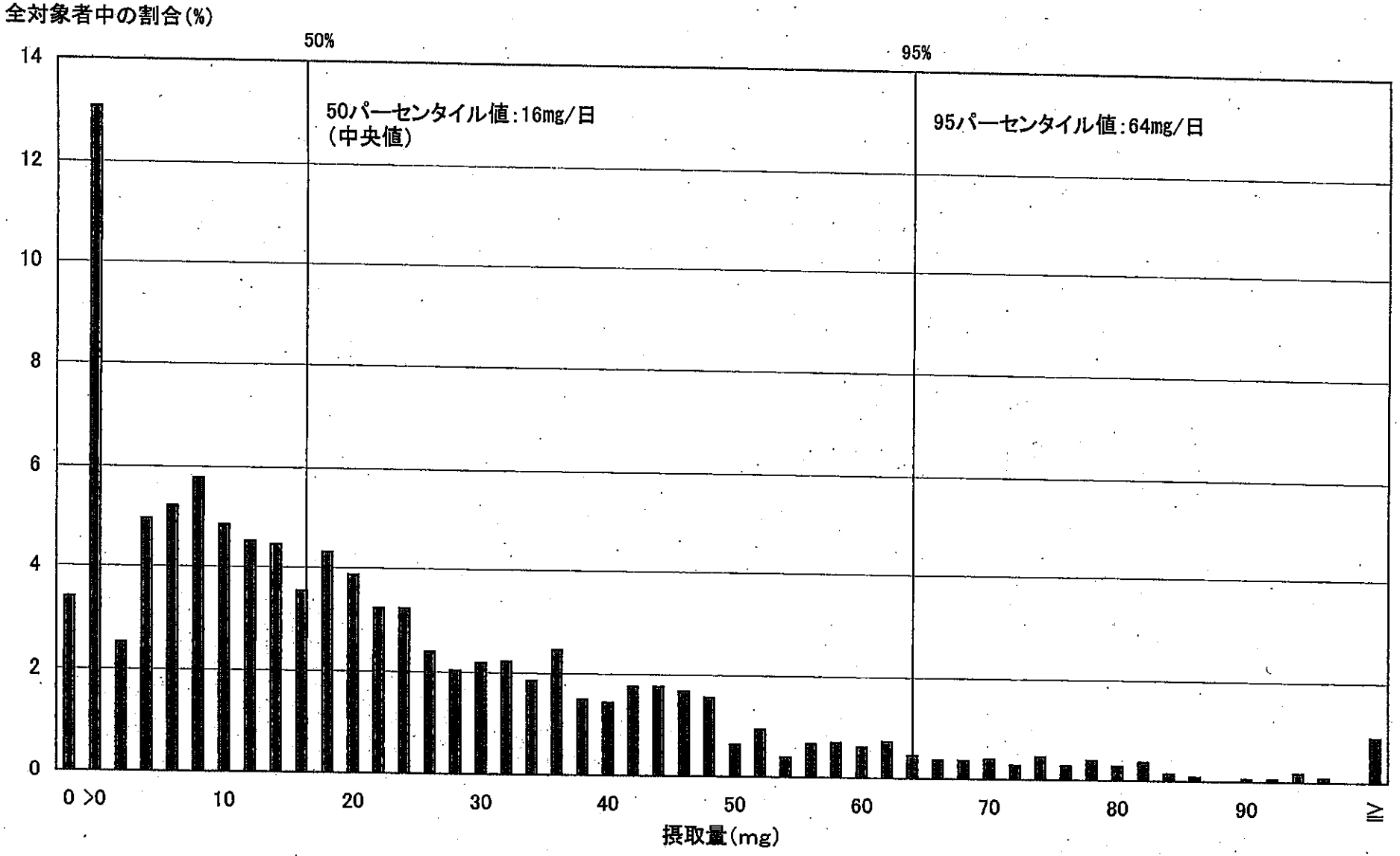
別紙2-1

平成14年国民栄養調査に基づく大豆由来食品からの大豆イソフラボン摂取量分布(総数)



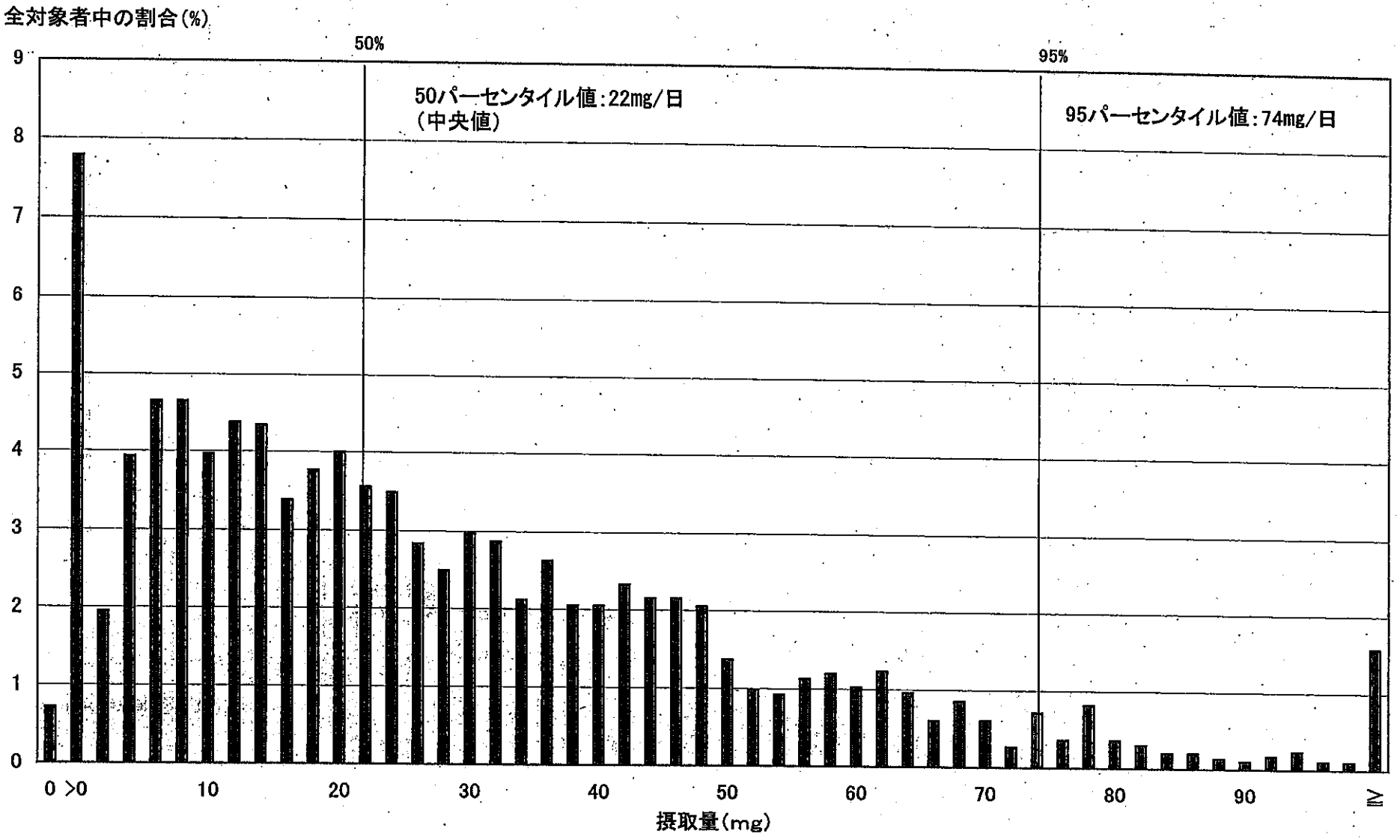
別紙2-2

平成14年国民栄養調査に基づく大豆由来食品からの大豆イソフラボン摂取量分布（女性15歳～59歳）



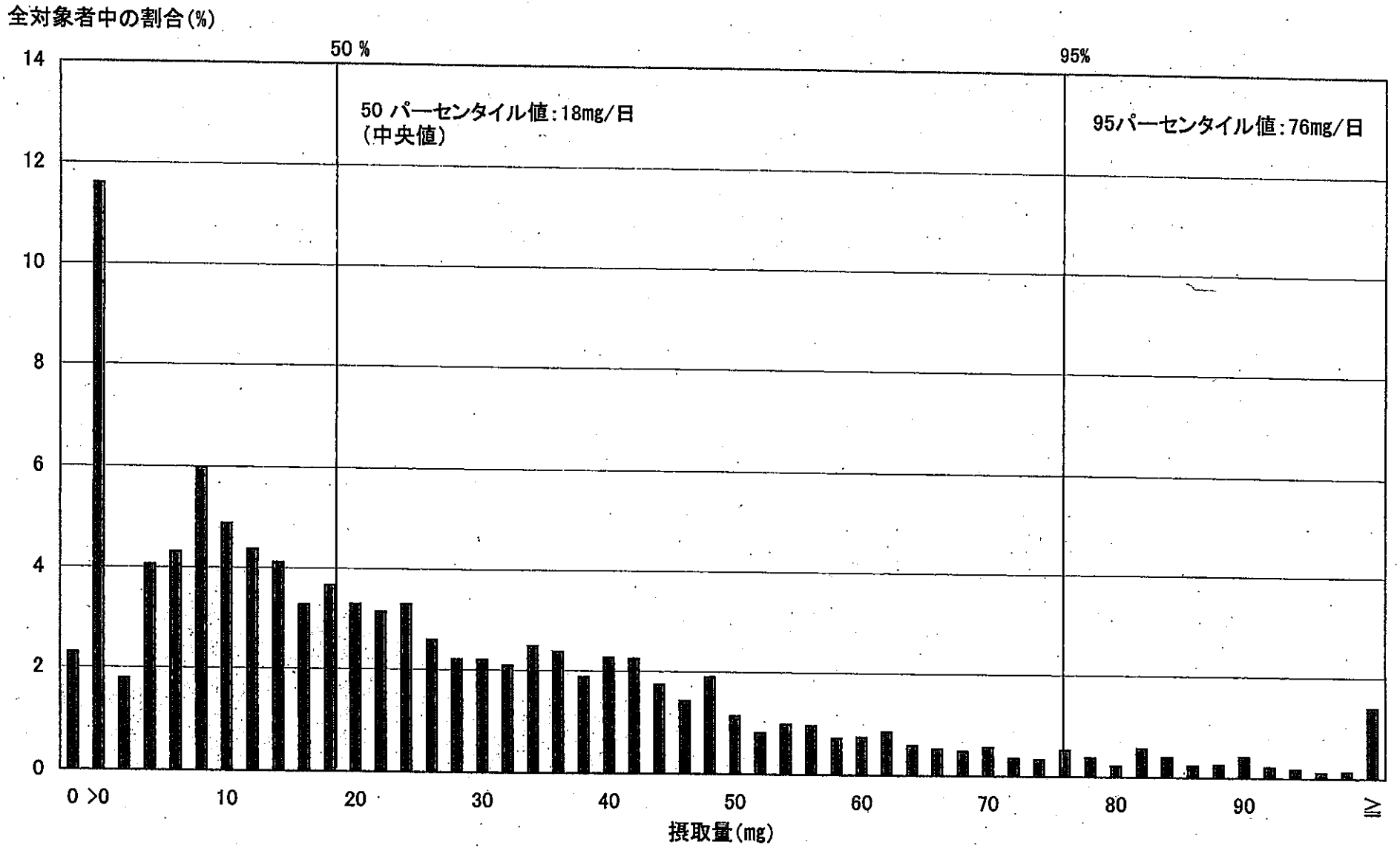
別紙2-3

平成14年国民栄養調査に基づく大豆由来食品からの大豆イソフラボン摂取量分布(女性50歳以上)



別紙2-4

平成14年国民栄養調査に基づく大豆由来食品からの大豆イソフラボン摂取量分布（男性15歳以上）



安全性に関する試験報告(閉経前女性)一覧

別紙3-1

文献番号	大豆イソフラボン摂取量				試験内容の情報		
	日常摂取量(mg/日)	上乗せ摂取量(mg/日)	総摂取量(mg/日)	試験データの取捨選択理由	人数、年齢	人種(不明の場合、試験実施地)	摂取期間(月経周期の倍数で表示)
44-1	-	28.1	28.1	E2変動P<0.05	6名(20-29歳)	不明(USA)	1
44-2	-	25.0	25.0	被験者3名のみ			
44-3	-	14.4	14.4		6名(20-29歳)	不明(USA)	1
45-1	10	20.0	30.0	データの起/終点なし(変動値のみ)			
45-2	10	40.0	50.0	データの起/終点なし(変動値のみ)			
45-3	10	50.0	60.0	被験者3名のみ			
46-1	-	36.2	36.2	E2データの起/終点なし(変動%のみ)			
46-2	-	27.7	27.7	E2データの起/終点なし(変動%のみ)			
49-1	-	38.0	38.0		16名(29.7-64.6歳)	不明(USA)	2
49-2	-	38.0	38.0	経口避妊薬服用者			
48	-	37.4	37.4	月経周期にあわせたホルモン値の分析データ、月経周期のデータなし			
50	-	45.0	45.0	ホルモン値の分析データ、月経周期のデータなし			
51	-	45.0	45.0	ホルモン値の分析データ、月経周期のデータなし			
52	4	55.0	59.0	ホルモン値の分析が黄体期			
53-1	-	10.0	10.0	用量別のクロスオーバー試験、起点のE2データなし			
53-2	-	64.0	64.0	同上			
53-3	-	128.0	128.0	同上			
55-1	15.8	56.9	72.7	55-2の被験者と重複			
55-2	18.4	57.3	75.7	55-1の試験の内、血清採取時期が揃っているデータを採用、E2変動P=0.1	21名	日本人	2
54	-	154.0	154.0	E2の変動P=0.01、E2データの起/終点なし(変動%のみ)			
56	1	75.0	76.0	ホルモン値の分析データなし			
57	-	147.0	147.0	E2変動P=0.03、月経周期変動P=0.06	6名(22-29歳)	コーカシアン4名、アフリカンアメリカン1名、ヒスパニック1名	1

安全性に関する試験報告(閉経前女性)一覧

別紙3-2

文献番号	大豆イソフラボン摂取量			卵胞期のE2(pg/ml)				摂取前後のE2の変動			月経周期				摂取前後の月経周期の変動	
	日常摂取量(mg/日)	上乗せ摂取量(mg/日)	総摂取量(mg/日)	摂取前	SE/SD*	摂取後	SE/SD*	変動(記載または摂取前後の差)	摂取前後のE2の差(pg/ml)	摂取前後のE2の差(摂取前に対する摂取後の%変動)	摂取前(日)	SE/SD*	摂取後(日)	SE/SD*	変動(記載または摂取前後の差)	摂取前後の月経周期の差(摂取前に対する摂取後の%変動)
44-1	-	28.1	28.1	69.40	8.30	97.20	27.80	+27.80	+27.80	+40.1%	27.5	2.4	29.0	2.0	+1.50	5.5%
44-2	-	25.0	25.0													
44-3	-	14.4	14.4	83.30	11.10	72.20	8.30	-11.10	-11.10	-13.3%	33.0	4.0	32.0	5.0	-1.00	-3.0%
45-1	10	20.0	30.0													
45-2	10	40.0	50.0													
45-3	10	50.0	60.0													
46-1	-	36.2	36.2													
46-2	-	27.7	27.7													
49-1	-	38.0	38.0	144.90	85.90	131.10	95.90	-13.80	-13.80	-9.5%	29.2	3.7	29.3	3.9	+0.10	0.3%
49-2	-	38.0	38.0													
48	-	37.4	37.4													
50	-	45.0	45.0													
51	-	45.0	45.0													
52	4	55.0	59.0													
53-1	-	10.0	10.0													
53-2	-	64.0	64.0													
53-3	-	128.0	128.0													
55-1	15.8	56.9	72.7													
55-2	18.4	57.3	75.7	98.00	85.00	65.40	51.70	-32.60	-32.60	-33.3%	29.0	4.2	32.4	8.7	+3.40	11.7%
54	-	154.0	154.0													
56	1	75.0	76.0													
57	-	147.0	147.0	186.90	99.30	35.50	range22-57	-151.40	-151.40	-81.0%	28.3	1.9	31.8	5.1	+3.50	12.4%

*SE : standard error(標準誤差)
SD : standard deviation(標準偏差)

別紙 4

大豆イソフラボンが血清 E2 濃度及び月経周期に与える影響

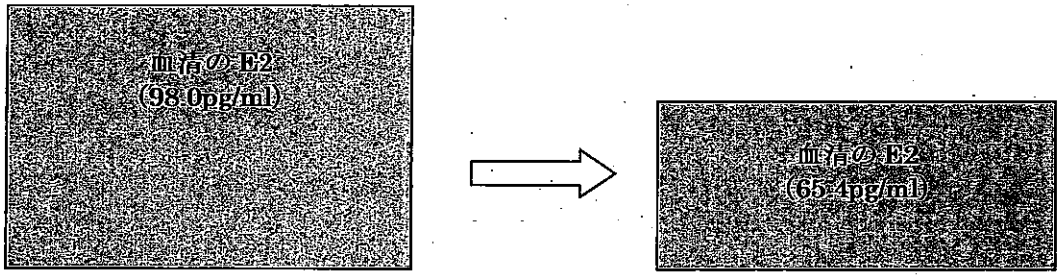
(1)豆乳 400ml(大豆イソフラボン 57.3 mg/日(アグリコン換算))摂取による影響(卵胞中期)

通常食生活に加えて、約 400ml/日の豆乳(総大豆イソフラボン摂取量 121.2 mg/日(アグリコン換算 75.7 mg/日):豆乳以外の食品によるものを含む)を 2 月経周期摂取した場合のホルモン値(血清採取卵胞期 9～12 日)及び月経周期の変動 55)

約 400ml/日の豆乳（大豆イソフラボン 57.3 mg/日（アグリコン換算)）摂取により、血清 E2 は約 33%低下し、月経周期は 12%延長した。

＜通常の食生活＞
総イソフラボン 29.5 mg/日
(アグリコン換算　18.4 mg/日)

＜通常の食生活＋豆乳約 400ml/日＞
総イソフラボン　121.2 mg/日
(アグリコン換算　75.7 mg/日)



(2)豆乳 1000ml(大豆イソフラボン 147 mg/日(アグリコン換算))摂取による影響(卵胞後期)

毎食時 12 オンス(約 355ml)の豆乳(1065ml/日、大豆イソフラボン摂取量 215.6 mg/日(アグリコン換算約 147 mg/日))を 1 月経周期摂取した場合のホルモン値(血清採取卵胞期 12～14 日)及び月経周期の変動 57)

約 1000ml/日の豆乳（大豆イソフラボン 147 mg/日（アグリコン換算)）摂取により、血清 E2 は約 81%低下し、月経周期は 12%延長した

＜通常の食生活＞
(大豆イソフラボン摂取量不明)

＜通常の食生活＋豆乳約 1000ml/日＞
総イソフラボン　215.6 mg/日
(アグリコン換算　147.0 mg/日)